The Royal College of Pathologists of Australasia

MEDIA RELEASE **23 JULY 2021**

Emerging real-world evidence highlights risk of missing COVID-19 cases with rapid antigen tests

As more real-world evidence surrounding rapid antigen tests comes to light, the Royal College of Pathologists of Australasia reaffirms its position against the widespread use of these tests in Australia and New Zealand, due to the limitations in their sensitivity. The RCPA strongly urges that careful consideration, further monitoring and evidence is required before considering the implementation of rapid antigen testing in both countries.

Dr Michael Dray, President of the RCPA, says that there is growing evidence which shows that rapid antigen tests should not be used for detection of COVID-19 in low prevalence settings.

"We are becoming increasingly concerned at the level of commentary that promotes rapid antigen tests for the detection of COVID-19, despite the evidence. When put into real-world settings, the evidence shows that there are significant differences between the actual performance of rapid antigen tests and manufacturers' claimed test performance. Whilst they may have quicker turnaround times for obtaining a result than current PCR testing methods, ranging from 15-30mins, rapid tests have a relative increased chance of giving both false negative and false positive results compared with Polymerase Chain Reaction (PCR) molecular tests. In countries with low prevalence of COVID-19 infection such as Australia and New Zealand, we simply cannot risk individuals receiving false negative or false positive results.

"In addition to these significant shortcomings, these Rapid Point of care tests are subjective, and also are not scalable, so it is not practical to use these in screening large numbers of people. They also would introduce many other challenges in terms of interpretation, and documentation and notification of results to health departments, which are not issues for laboratory-based tests.

"If our goal is to ensure SARS-CoV-2-free, or at least very low level, environments by allowing those who test negative to re-join the community and resume their usual activities, then false-negative results are not acceptable as the risk of releasing infectious individuals back into the community is too high. It is therefore essential that we only use screening tools which have the highest possible sensitivity since this is the only parameter that reflects the rate of cases who erroneously test negative, irrespective of the disease prevalence. Therefore, the preferred method for COVID-19 diagnosis in Australia and New Zealand, remains as the PCR molecular tests for the SARS-COV-2 virus, due to its high sensitivity and specificity," said Dr Dray.

In the UK, the Innova SARS-CoV-2 antigen rapid lateral flow test was one of the first to pass the tests set by Public Health England (PHE) and was bought in large quantities by the UK government. Sensitivity was 96% in the manufacturer validation (in people with symptoms), 74% in known infected people from a community setting, but when evaluated independently was but just 40% in the prospective evaluation by Garcia-Fiñana and colleagues in an asymptomatic community setting.[1]

As part of a recent study carried out in Liverpool, UK, the Innova test was offered to all adults attending asymptomatic testing sites. Of the 5,869 participants, 74 of them tested positive for SARS-CoV-2 using the PCR test (prevalence 1.3%). The overall sensitivity of the rapid test

[1,2] BMJ 2021;374:n1637 http://dx.doi.org/10.1136/bmj.n1637

was 40.0% (95% confidence interval 28.5% to 52.4%), meaning that it detected only four in 10 people who tested positive by PCR, therefore missing six.[2]

Dr Lynette Waring, Chair of the RCPA's microbiology advisory committee, says that rapid antigen tests were better at detecting COVID-19 in people with symptoms.

The balance between benefit and harms from testing is dependent on prevalence of SARS-CoV-2. A recent Cochrane review* assessed the diagnostic accuracy of point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection. This review found that if the SARS-CoV-2 prevalence in Australia was 0.5% (which is a lot higher than it is currently), then between 7 in 10 and 9 in 10 positive results would be false positives, and between 1 in 2 and 1 in 3 positive cases would be missed by the best rapid antigen tests, compared to by PCR.[3] If infectious individuals were cleared to return into the community then the implications on case numbers could be far reaching.

"The review also found that antigen tests were better at identifying COVID-19 in people with symptoms than they were in people without symptoms. This is especially concerning with the current Delta variant circulating in our communities, in which people are often asymptomatic during their infectious period," said Dr Waring.

Most of the studies included in the Cochrane review were from Europe and the USA and assessed the accuracy of rapid antigen tests. The first version was published in August 2020 and included 22 studies. The updated review now includes evidence from 64 studies and reveals that in people with symptoms, on average 72% of people who had COVID-19 were correctly identified by the antigen tests as being infected, meaning 28% weren't identified. In people without symptoms, on average, the antigen tests correctly identified 58% of those who were infected, meaning 42% were not identified. The tests also performed best in the first week after symptoms began when they identified 78% of people who had COVID-19.[4]

"One recognised indication for antigen testing would be unavailability of PCR testing, as has sadly occurred even in high-income countries overseas. Australia fortunately is currently breaking levels for its rates of PCR tests, with New South Wales alone recording 85,185 PCR tests in just one day.

"Considering the limitations in test sensitivity and the potential for rapid transmission in susceptible populations, particularly in hospital settings, careful consideration is required for implementation of antigen testing in a low prevalence setting. The College will continue to monitor the evidence as it becomes available and will update its position if and when required," said Dr Dray.

*A Cochrane Review is a systematic review of research in health care and health policy. The reviews are updated to reflect the findings of new evidence when it becomes available because the results of new studies can change the conclusions of a review.

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[3] [4] https://doi.org/10.1002/14651858.CD013705.pub2

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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