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Position Statement

Subject:	**COVID 19 Antigen and Point of Care Testing**
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The Royal College of Pathologists of Australasia states that:

Due to its high sensitivity and specificity, the preferred method for COVID-19 diagnosis is PCR molecular testing for the SARS-COV-2 virus. In Australia and New Zealand, given the availability of reliable high-throughput, fast, PCR molecular testing, COVID-19 rapid antigen tests are currently not considered to be suitable for widespread use. This is especially important due to the low prevalence of COVID-19 currently present in both countries. This may change in defined specific situations as data on performance, assay availability and regulatory approval become available and if the prevalence of COVID-19 infections in our populations greatly increases.

Background

PCR molecular tests for SARS-COV-2 virus for the diagnosis of COVID19 (the disease) are both highly sensitive and specific and are the mainstay of testing. Rapid PCR tests are also available for use. Turnaround time (TAT) for laboratory-based PCR testing in Australia and New Zealand is relatively fast, and capacity is presently increasing to meet surge requirements.

Specific comments on COVID 19 Antigen Testing

- COVID19 Antigen Tests are immunoassays that are generally performed on nasopharyngeal swabs. These tests can be performed either in a laboratory or at the Point of Care (Rapid Antigen Tests).
- Some require specific devices to read the results, which increases their accuracy, however, this increases the TAT and cost of the tests.
- Rapid Antigen Tests are ‘single patient’ tests that cannot go on high-throughput automated systems, unlike current PCR molecular tests, so are subject to variations in individual operator interpretation. Lack of training and use in uncontrolled environments could lead to unreliable results.
- Rapid antigen tests have quicker TATs (15-30 min) than PCR tests.
- Rapid antigen tests are less sensitive (the ability to detect the disease when present) compared with gold standard PCR molecular tests in detecting the relevant virus. The sensitivity of clinically useful Rapid Antigen Tests has been reported to be 50- 94%. This means they are more likely to cause false negative results than PCR, which is critical when performed in a low prevalence setting, leading to patients with active COVID-19 being missed.
- The specificity (the ability to correctly generate a negative result for people who don't have the disease) of Rapid Antigen Tests, are usually reasonably high (>97%),

however, very few have undergone stringent evaluation. Notwithstanding, in a low prevalence population, many of the positive results would be false positives.

- More evidence is needed on real-world performance and operational aspects of Rapid Antigen Tests but it appears they are most likely to perform well in patients with high viral loads which usually appear in pre-symptomatic (1-3 days) and early symptomatic (within the first 5-7 days of illness) persons. PCR tests detect virus at much lower levels, hence will remain positive for longer both prior to symptoms and after symptoms are present.
- Patients who present after 5-7days of infection, or if asymptomatic, are more likely to have lower viral loads and thus are more likely to get a false-negative result with Rapid Antigen Tests, with the risk of facilitating spread.
- In a low prevalence setting, such as currently in Australia and New Zealand, the use of these tests will have a higher risk of false positives, as well as false negatives.
- Evaluation of the tests in a low prevalence setting is challenging and may be an unreliable indicator of test performance in practice.
- To date there has been limited independent evaluations of these tests by regulatory agencies and laboratories thus caution should be used in the adoption of these tests for the management of the COVID-19 pandemic in Australia and New Zealand at this time.
- There may be some use for these tests in specific scenarios which are discussed below.

Rapid Antigen Testing should NOT be used in settings or populations with low expected prevalence of the disease due to the risk of both false positive and false negative results. More data from high quality studies confirming the sensitivity and specificity (>99%) for each assay is required. Specific situations where Rapid Antigen Tests are NOT recommended in low prevalence populations include: screening points of entry, blood donation and elective surgery.

Use of Rapid Antigen Tests in an uncontrolled environment with limited training could lead to unreliable results.

Evaluation of the tests in the present low prevalence setting is challenging and may be an unreliable indicator of true test performance.

In a <u>high prevalence/ high risk setting</u> (which is not the present situation in Australia and New Zealand) a high sensitivity/ high specificity rapid antigen assay, following external validation of the test performance, and ensuring optimal transport, storage and testing procedures are followed, may be used:

- To respond to suspected outbreaks of COVID19 in remote settings where PCR molecular testing is not readily accessible. A positive result would need to be confirmed by PCR molecular testing.
- To support PCR confirmed outbreak investigations. (ie closed or semi-closed groups including schools nursing homes, cruise ships, prisons etc). This could be used to isolate positive cases and initiate contact tracing and prioritise sample collection for negative cases for PCR confirmation 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, etc

- Testing asymptomatic contacts of cases, though a negative case should not remove the person from quarantine

Public health and laboratory authorities in Australia are evaluating various rapid antigen tests and will define the appropriate scenarios for their use in our current low-incidence setting.

Self-collected & Self- administered Point of Care Tests:

- Self-collected & Self-administered Point of Care Tests are a public health risk and are not recommended.

References

1. Antigen-detection in diagnosis of SARS-Cov-2 infection using rapid immunoassays-Interim guidance, WHO,11 September 2020
2. Rapid Antigen Testing for SARS-CoV-2

   https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html
3. COVID-19 testing in Australia - information for health professionals

   https://www.tga.gov.au/covid-19-testing-australia-information-health-professionals
4. Basile K et al. Point-of-care diagnostics for respiratory viral infections. Expert Reviews in Molecular Diagnostics 2018; 18(1):75-83.