Public Health Laboratory Network –
Communicable Diseases Network Australia
Joint Statement on SARS-CoV-2 Rapid Antigen Tests

The Public Health Laboratory Network (PHLN) and Communicable Diseases Network Australia (CDNA) continue to monitor and consider the potential for use of SARS-CoV-2 rapid antigen testing in Australia. At this time, PHLN and CDNA advise that, rapid antigen tests should only be used with medical oversight under public health direction in specific settings.

Diagnostic testing for SARS-CoV-2 is vital to suppressing COVID-19 transmission in Australia. Reverse Transcription Polymerase Chain Reaction (RT-PCR) is the gold standard SARS-CoV-2 diagnostic test in Australia. RT-PCR tests are very sensitive and detect the smallest genetic fragments of the SARS-CoV-2 virus in a respiratory tract sample. Currently, RT-PCR is accessible and widely available in Australia.

In addition, laboratory-based serology (blood) tests are also available in Australia. These tests detect past COVID-19 infection. Serology tests detect antibodies to the SARS-CoV-2 virus, which the body produces as part of its immune response.

Recently, manufacturers have developed SARS-CoV-2 rapid antigen tests as an alternative to RT-PCR. The manufacturers intend for these tests to be used at the point-of-care (or near person care). Similar to RT-PCR, antigen tests require collection of a respiratory tract sample. However, in contrast to RT-PCR, the design of these tests is to detect the presence of viral protein produced by SARS-CoV-2. In doing so, the tests can provide a presumptive diagnosis of COVID-19 in persons with suspected infection. PHLN and CDNA note that the advantages of rapid antigen tests may include:

- ease-of-use testing method;
- rapid turnaround from specimen collection to results;
- lower relative cost to RT-PCR (depending on frequency of use);
- improved accessibility for populations far removed from urban pathology laboratories; and
- the potential for wide scale testing.

Rapid antigen tests can provide a result within 15–30 minutes. However, they have inferior analytical performance compared to the gold standard RT-PCR for the diagnosis of COVID-19. Further, there is considerable variability in the performance between the different rapid antigen tests.

Noting this, PHLN and CDNA advise there are specific circumstances in which rapid antigen tests may be used provided users appropriately manage risks. Users should only conduct rapid antigen tests with medical oversight and under public health direction, in strict accordance with the manufacturers’
instructions. Further, use should accord with relevant jurisdictional and national laws and regulations.¹ This is on the basis that:

i. rapid antigen tests are generally less sensitive and may be less specific compared to RT-PCR. This is based on published evidence;
ii. current testing using RT-PCR is accessible and widely available;
iii. point-of-care RT-PCR is available in many settings where users require a rapid turnaround time;
iv. there is a lack of published evidence on the performance of rapid antigen tests in ‘real life’ settings;
v. in some cases, rapid antigen tests require specific skills and a quality framework for test performance, interpretation and record keeping;
vi. there are currently specific drawbacks associated with local rapid antigen testing, including:
   • lack of quality assurance programs;
   • lack of clinical experience in use for diagnosis of SARS-CoV-2 (compared to influenza and respiratory syncytial virus, for example);
   • requirement for follow-up confirmatory testing;
   • potential for failure to notify public health and consequent lack of public health follow-up and transmission if the user does not perform confirmatory testing for a positive result;
   • potential for on-going transmission if an antigen result is a false negative and if the user does not perform confirmatory testing; and
   • the potential for incomplete data capture and therefore inaccurate COVID-19 case counts; and
vii. resolution of many of these issues (e.g. quality assurance proficiency testing programs) is required prior to broader introduction of rapid antigen tests.

Background
Diagnostic testing for SARS-CoV-2 is central to controlling the COVID-19 pandemic in Australia. Testing for COVID-19 must accord with epidemiological and clinical criteria in the COVID-19 CDNA National Guidelines for Public Health Units (National Guidelines).² The current approach to testing for COVID-19 focuses on testing people with clinically compatible symptoms described by the National Guidelines.

Supplementary and novel testing technologies continue to emerge in both the international and domestic markets. As a result, PHLN has established a working group with invited CDNA members. The working group will monitor emerging SARS-CoV-2 testing technologies and their potential application in the Australian context. As part of their scope, the working group is reviewing rapid antigen tests.

On 11 September 2020, the World Health Organization (WHO) published the interim guidance Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays.³ The WHO advises that antigen tests may be appropriate for use in settings where RT-PCR is unavailable, or prolonged turnaround times preclude clinical utility. Importantly however, for Australia, this guidance does not recommend the use of rapid antigen tests in settings or populations with low expected prevalence of

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³ https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays
Further information on rapid SARS-CoV-2 antigen testing is available in the PHLN Guidance on laboratory testing for SARS-CoV-2\(^5\) and on the TGA website.\(^1\)

Additional information on the use of COVID-19 point-of-care tests in the Australian setting is available on the National Pathology Accreditation Advisory Council website.\(^6\)

**Limitations of SARS-CoV-2 rapid antigen tests**

Like all tests that detect infections, results obtained from rapid antigen tests and require interpretation by a medical practitioner or suitably qualified person.\(^3\) They will accurately identify the SARS-CoV-2 infection and/or requirement for further testing. This is to minimise the risk of an incorrect public health response based on SARS-CoV-2 rapid antigen test results. Misinterpretation of results can have significant public health consequences, including inappropriate management of the patient and their contacts, particularly if confirmatory testing is not done concurrently. This is a particular issue in the event of false-negative results, or where positive results are misinterpreted as “false” by an untrained user and, the infected person continues to work in a high-risk setting. Medical practitioners should have a working understanding of the tests used in the diagnosis of COVID-19. This includes understanding their use and limitations in order to provide appropriate advice and treatment.

Most rapid antigen detection tests are designed to test people with symptoms compatible with COVID-19. However, in some cases manufacturers claim their test may be used for asymptomatic screening. The names of antigen tests registered for legal supply in Australia by the TGA are on the Australian Register of Therapeutic Goods.\(^7\)

PHLN and CDNA discourage the use of rapid antigen tests when the prevalence of COVID-19 is low. This is noting analytical and epidemiological factors affect the test’s predictive value and overall performance. However, in specific settings, there may be a role for these tests as a screening or initial diagnostic tool. This is in cases where the pre-test probability of a population, both symptomatic and asymptomatic, is higher. The main utility of these tests may be in situations where users consider a false negative result to be a reasonable risk. For example, where the negative results has minimal impact on the management of the individual. Users may employ these tests as part of a public health response, where the rapid detection of positive cases will be of benefit. Further work on the specific public health application of these tests, and a determination on acceptable sensitivity is being rapidly undertaken. This will inform the evolution of PHLN and CDNA’s position on the use of SARS-CoV-2 rapid antigen tests.

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\(^4\) This can include screening at point of entry, blood donation, and elective surgery.


Recommendations

- PHLN and CDNA agree there is a need to explore new testing technologies and approaches. This is to remain agile, and at the forefront of emerging testing technology and to identify where value could be added to Australia’s COVID-19 response;

- PHLN and CDNA note that rapid antigen tests may have a role as a screening test for COVID-19 in certain contexts and settings, to be determined by jurisdictional public health authorities. This will be complementary to, and not a replacement for, RT-PCR testing;

- PHLN and CDNA caution against the wide-scale implementation of any type of new testing technology before appropriate post-market evaluation is undertaken. PHLN and CDNA note there are many issues to consider, including supply chains, logistics, cost, ease-of-use, test performance, data security and privacy;

- PHLN and CDNA recommend only a medical practitioner or suitably qualified person should perform or supervise the use of rapid antigen tests; and

- PHLN and CDNA urge the continued and rigorous evaluation of emerging testing technologies prior to use. This helps safeguard Australia’s world-leading testing capacity for COVID-19, and ensures that the highest quality testing technology is available to support the Australian community.