Australian Government
Department of Health
Therapeutic Goods Administration

COVID-19 testing in Australia - information for health professionals

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Tests for COVID-19 aim to detect the causative virus, SARS-CoV-2, or an immune response to SARS-CoV-2.

The reliability of COVID-19 tests is uncertain due to the limited evidence base. Available evidence mainly comes from symptomatic patients, and their clinical role in detecting asymptomatic carriers is unclear.

The indications for conducting a COVID-19 test have changed through the course of the pandemic. See the current suspect case definition (https://www1.health.gov.au/internet/main/publishing.nsf/Content/cdna-song-novel-coronavirus.htm) and the testing criteria (https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/what-you-need-to-know-about-coronavirus-covid-19#testing) on the Department of Health website.

The three main types of SARS-CoV-2 tests are:

- Nucleic acid detection tests - to detect SARS-CoV-2 viral (Ribonucleic acid) RNA;
- Rapid antigen tests - to detect antigen viral proteins from the SARS-CoV-2 virus; and
- Serology tests - to detect IgM and/or IgG antibodies against SARS-CoV-2.

Nucleic acid PCR tests

Reverse transcriptase Polymerase Chain Reaction (PCR) tests detect SARS-CoV-2 nucleic acid (RNA). Most of these assays typically take several hours (including specimen processing time) to generate results, and require complex laboratory equipment and trained technicians. There are now some near patient SARS-CoV-2 PCR instruments available that can be used outside of a laboratory. These systems can provide quicker results, but cannot do as many tests at once.

PCR tests are currently considered to be more clinically sensitive than serology assays for detecting early infections and, because they directly detect viral RNA, they are an indicator for viral shedding. The extent to which a positive PCR result correlates with the infectious state of an individual is still being determined. Clinical resolution and in special situations, consecutive negative PCR tests in a previously positive individual are currently being used as criteria

(https://www1.health.gov.au/internet/main/publishing.nsf/Content/cdna-song-novel-coronavirus.htm) when considering release from isolation. However, this may change with increasing knowledge around SARS-CoV-2.

The Peter Doherty Institute for Infection and Immunity has completed a validation study of the Beijing Genomics Institute SARS-CoV-2 Real time PCR test kit and associated instrumentation and reagents (https://www.health.gov.au/resources/publications/post-market-validation-of-the-beijing-genomics-institute-bgi-sars-cov-2-real-time-pcr-platform).

Rapid antigen tests for viral protein

Rapid antigen tests intended for use at the point-of-care detect the presence of viral protein from SARS-CoV-2 and may be used in the diagnosis of a SARS-CoV-2 infection in a symptomatic patient. COVID-19 antigen tests are generally intended for use with nasopharyngeal, throat or nasal swabs and testing should be performed by health professionals in accordance with the manufacturer's instructions for use.

While rapid antigen tests can provide a result within 15-30 minutes, they are generally considered to be less sensitive than a PCR test which is still currently the gold-standard in SARS-CoV-2 diagnosis.

Rapid antigen tests are best performed within the early stages of acute infection, when viral load is at its highest levels (i.e. within the first 5-7 days from symptom onset), after which antigen levels may drop significantly. In conjunction with clinical findings, a positive result is generally considered to be accurate, however further testing by PCR may be required in some cases. A negative result in a symptomatic patient, would require further confirmatory testing via PCR testing. The clinical utility of rapid antigen tests in screening asymptomatic persons has not been established.

Serology antibody tests

The TGA has received and undertaken an expedited assessment of a number of applications for laboratory-based serology immunoassay tests and point-of-care (often referred to as PoC or PoCT) serology tests that utilise lateral flow immunoassay technology.

Point-of-care serology tests are intended to detect IgG and/or IgM antibodies to SARS-CoV-2 from venous or finger prick blood samples that are placed on a test strip. These tests look similar to common pregnancy tests. Results take about 15–30 minutes.

There is a window period between virus infection and the production of IgM and IgG antibodies, and the sensitivity and specificity of IgM/IgG antibody tests early in SARS-CoV-2 infection is not well characterised. Antibodies can take up to two weeks or more to become detectable after infection with SARS-CoV-2. Because antibody tests do not detect active viral shedding, they cannot detect if an individual is infectious. Though they provide some useful information when combined with the clinical picture, a suggestive clinical picture plus a positive point-of-care may be considered sufficient for a presumptive positive diagnosis and subsequent management.

Human coronaviruses circulate frequently every year and cause a common cold type illness. Cross reaction with antibodies formed by current and past exposure to seasonal human coronavirus infections can cause false-positive results. Serology tests can also fail to detect COVID-19 if testing is performed in the acute phase of the infection prior to the development of detectable antibodies.

Serology antibody assays generally provide historic information about viral exposure. They can indicate whether an individual has past exposure to SARS-CoV-2. It is not yet evident that the detection of antibodies reflects the presence of protective immunity, so the detection of antibodies may not exclude remaining infectivity in a patient.

COVID-19 test performance

COVID-19 is an emerging viral infectious disease. There is limited evidence available to assess the accuracy and clinical utility of available COVID-19 tests.

Due to the urgent nature of the COVID-19 pandemic, a number of SARS-CoV-2 tests have undergone an expedited assessment by the TGA to enable their legal supply in Australia. These expedited assessments are based on the limited clinical and performance data currently available. All SARS-CoV-2 tests currently approved for supply (//www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-australia) are required to provide updated evidence to support the ongoing safety and performance of the tests to the TGA.

The TGA is conducting a post-market review (//www.tga.gov.au/post-market-review-covid-19-point-care-tests) of all approved COVID-19 point-of-care serology tests to verify their performance and inform their best use. The Department of Health has engaged the Peter Doherty Institute to assist in the post-market validation of these tests.

Note: In Australia, the supply of self-tests for most serious infectious diseases, including self-tests for COVID-19, is prohibited under the Therapeutic Goods (Excluded Purposes) Specification 2010 (https://www.legislation.gov.au/Details/F2014C01309).

The TGA will take action in relation to any report of poor or faulty performance of these devices. Reports can be submitted via the TGA website (//www.tga.gov.au/reporting-problems).

Category: Medical devices/IVDs
Tags: COVID-19 tests
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