



POSITION STATEMENT

COVID-19 Point-of-Care Testing

Position

The Pharmacy Guild of Australia (the Guild) supports community pharmacies accessing point-of-care (PoC) tests that are approved by the Therapeutic Goods Administration (TGA) and listed on the Australian Register of Therapeutic Goods (ARTG) for:

1. the provision of surveillance PoC testing within the pharmacy or via outreach services to:
 - a. pharmacy staff
 - b. asymptomatic patients
2. the sale and supply of self-testing kits to consumers

The Guild acknowledges that Polymerase Chain Reaction (PCR) testing is the gold standard for identification of SARS-CoV-2 infection, however, supports the use of other types of surveillance PoC testing in areas where COVID-19 is circulating in the community. PoC testing, including self-tests, will provide assurances for businesses and the general public that a person is not infected and can safely work, study, or go about their usual activities.

The Guild supports the provision of quality and safe PoC testing services by community pharmacies. For rapid antigen PoC testing services, we recommend pharmacies consider the TGA guidance¹ for implementing COVID-19 RA PoC testing including but not limited to:

- having protocols in place to manage safety of the pharmacist and the person being tested including infection control procedures and access to Personal Protective Equipment (PPE)
- ensuring all staff conducting the test are appropriately trained
- management of positive results and arrangements for confirmatory tests
- notification of positive results to public health authorities
- complying with any state and territory requirements for COVID-19 testing

The Guild acknowledges that community pharmacies may not wish to provide testing services due to the risk of infection of staff and the subsequent impact on their pharmacy business and ability to ensure access to medicines for their communities. Community pharmacies should be able to charge a professional fee for conducting a testing service, payable either by the consumer, their employer, or through a reimbursement scheme.

The Guild supports the sale and supply of self-testing kits to consumers from community pharmacy. Community pharmacists and their staff will be trained in the use of the kits and will be able to give high quality advice and instructions to consumers, including how to conduct the test, interpretation of the result, and what obligations they have if they receive a positive result. Consumers will have access to a trained health professional to answer any of their questions.

¹ [COVID -19 Rapid Antigen Point of Care Testing \(tga.gov.au\)](https://www.tga.gov.au/covid-19/rapid-antigen-point-of-care-testing)

National Secretariat



Background

COVID-19 rapid PoC tests

There are three kinds of Point of Care (PoC) rapid tests:

1. Rapid Antigen Tests for viral protein.

Rapid antigen (RA) PoC tests use throat or nose swabs to collect samples for testing. They provide results within 15-30 minutes and can detect the virus in the acute phase of infection, the week before symptoms appear until 7 days after, when the viral load is at its highest. They are generally considered to be less sensitive than a PCR test. Due to the potential for false negatives, and some false positive results, individuals may require a confirmatory PCR test.

2. Lateral Flow Immunoassay for IgG and/or IgM antibodies, are also known as **Serology Antibody Tests**.

Serology antibody tests use finger prick blood samples and look like a pregnancy test. They provide results in 15-30 minutes and are used to determine the presence of antibodies which indicate the body fighting the virus through either infection, or following vaccination. There are limitations to the use of serology antibody tests in the acute phase of infection, as it can take up to two weeks after infection for antibodies to be at a detectable level; for this reason, they are not recommended to be used as the sole basis for diagnosis of COVID-19. They can also result in false-positive results due to cross-reaction with other seasonal human coronaviruses that frequently circulate in the community causing common-cold like illnesses.

3. Nucleic Acid Tests for viral ribonucleic acid (RNA).

These tests use throat or nose swab generally to collect samples for testing. However, these tests require laboratory equipment and trained technicians. Only a few exist in Australia as PoC rapid tests. Community pharmacy could be a point to take the swab and send to lab for testing and results. Logistics of this would need to be investigated.

- a. Note: The “gold standard” test currently is the **polymerase chain reaction (PCR)** test, which is a type of Nucleic Acid Test.

Rapid COVID-19 tests will play a crucial role in helping Australians return to their workplaces. As early as November 2020 a University of Liverpool pilot program showed that regular rapid antigen testing of employees prior to attending work is an extremely effective guard against business losses (namely, working or business days lost to quarantine) in the COVID-19 world². For peak efficacy RA testing should be carried out every 3 days. This practice will allow businesses to return to normal trading, and to carry on trading with the knowledge that their locations and staff are COVID-19 free.

Use of COVID-19 rapid PoC tests in community pharmacy

Rapid antigen PoC tests are available in pharmacies in the UK and the Republic of Ireland, USA and France. The Canadian government is partnering with community pharmacies to provide RA PoC tests to small to medium size businesses and non-government organisations.

In line with the TGA advice, it is critical that PoC RA testing in community pharmacies only be provided to consumers who are asymptomatic due to the risk of infection of staff or other consumers if people who are potentially infectious or displaying COVID-19 symptoms attend the pharmacy. The TGA have developed guidance for businesses wanting to implement testing in the workplace, and this would apply

² [Liverpool, COVID-SMART Pilot Evaluation, 2021](#)

to community pharmacies providing testing to their own staff, the general public or through outreach services to other businesses³.

Community pharmacies will need to consider all aspects associated with providing a testing service including policies and procedures relating to PPE and infection control, staff training, resources, and costs. The consideration of risks and implications of infection of their staff and other consumers including impacts on the continuity of access to medicines is particularly important.

Supply of rapid tests for home or self-testing

The supply of home tests for COVID-19 through community pharmacy has been authorised from November 2021, subject to the TGA approval of home test kits and any regulatory changes.

The introduction of home tests into Australia's COVID-19 response is dependent on national vaccination rates, and the implementation of systems for reporting of self-test results, including any direction for individuals to have their result confirmed by PCR test.

Self-testing will be another option for consumers especially as restrictions are eased. It will allow them to test themselves if they develop symptoms or are a contact with someone with COVID-19, or if they are required to provide evidence of a negative result for employment, travel or other reasons.

Supply through community pharmacies will allow consumers to purchase test kits and receive professional advice on its correct use including specimen collection and how to interpret results.

Advertising of rapid antigen PoC tests

Advertising of RA PoC tests must comply with the Therapeutic Goods Advertising Code (TGAC). COVID-19 is a 'restricted representations' under the code however the TGA has issued legal permission which enables advertising of RA PoC tests subject to inclusion of certain statements and prohibition of others.

The TGA has clear guidance on how to advertise RA PoC tests and this should be referred to as the use of RA PoC tests changes over time⁴.

Related Policies

1. *Disease screening and condition management policy*
2. *Management Strategy for use of Oral COVID Treatments position statement*

Authority

Endorsed

National Council – October 2021

Reviewed

Policy and Regulation Sub-Committee – October 2021

³ [COVID-19 Rapid Antigen Tests - Guidance and checklist for businesses | Therapeutic Goods Administration \(TGA\)](#)

⁴ [Advertising COVID-19 Rapid Antigen Tests | Therapeutic Goods Administration \(TGA\)](#)