

## **Questions for Department of Health from SETSCoP Members – Jan 2022**

*Is there information about the difference between Novavax and other vaccines?*

The Department has developed resources about the Nuvaxovid (Novavax) COVID-19 vaccine, including two factsheets translated into 72 languages. The factsheets contain comprehensive information about Novavax, including: how it is manufactured, its safety and benefits, information for pregnant and breastfeeding women, children and people with weakened immune systems, precautions, and aftercare. Resources are available on the Department's website:

- <https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/approved-vaccines/novavax>
- <https://www.health.gov.au/resources/publications/covid-19-vaccination-information-on-nuvaxovid-novavax-covid-19-vaccine>
- <https://www.health.gov.au/resources/publications/covid-19-vaccination-after-your-nuvaxovid-novavax-vaccine>

*Will the number of vaccination and testing centres be increased due to the requirement to get the booster and increase in case numbers? (Long queues discourage clients getting vaccinated).*

Providing access to safe and effective COVID-19 vaccines to everyone in Australia seeking to be vaccinated is a key priority of the Australian Government. There are now over 9,700 places you can get vaccinated in Australia, including general practices, community pharmacies, Commonwealth Vaccination Clinics and state and territory vaccination clinics. The [COVID-19 Vaccine Clinic Finder](#) has details of all clinics, and is the best way to book a vaccination.

The Department is currently considering the need for additional GP-Led Respiratory Clinics where there may be services gaps.

*Is there information about RAT tests that can be shared? Eg. What is the difference between PCR and RAT tests? What do the different brands of RAT tests mean? Is it in multiple languages?*

What is the difference between PCR and RAT tests?

Two types of tests that can detect the presence of the SARS-CoV-2 virus (the virus that causes COVID-19) are: nucleic acid tests and rapid antigen tests.

### **Nucleic acid tests (which includes PCR tests)**

These tests detect the presence of the genetic material, called nucleic acids, of the actual virus. They are good at detecting the virus early in the infection and can sometimes even detect the

virus in a person before they become unwell. There are several types of nucleic acid tests that can be used to detect COVID-19, including polymerase chain reaction (PCR) tests.

PCR tests are generally considered better at detecting the presence of the COVID-19 and are currently the gold standard for diagnosis of COVID-19.

Nucleic acid tests are complicated to do and usually need specialist scientists to run the tests in a laboratory to get an accurate result. There are now some COVID-19 nucleic tests available that can be used outside of a laboratory by trained health professionals. Most of these systems give results quickly but cannot do many tests at once.

### **Rapid Antigen Tests**

These tests can detect the presence of specific proteins of the virus. They are most accurate when used to test symptomatic individuals. However, they are not as good at detecting virus as a nucleic acid test.

Rapid antigen tests are generally best performed within the first 7 days from when symptoms first appear. They are not as accurate if you do not have symptoms and can produce false negative or false positive results. Most tests produce a result within 10-20 minutes.

- ***Point of Care Tests***

Rapid antigen point of care tests are test that can be performed by health practitioners, or trained persons under their supervision. This ensures a suitable health practitioner, or trained person under their supervision is available to ensure an adequate sample is collected, the results are interpreted correctly, and immediate clinical advice and treatment can be provided if required.

For more information on supply of point of care rapid antigen tests see [rapid antigen point-of-care testing in Australia](#).

- ***Rapid Antigen Self-Tests (home use tests)***

These are tests that can be used unsupervised anywhere, such as at home or work, without the involvement of a health practitioner. The person collects the sample, performs the test and interprets the results by themselves.

For more information on supply of self-test rapid antigen tests see [COVID-19 rapid antigen self-tests in Australia](#). A list of all COVID-19 rapid antigen self-tests (home use tests) that are approved for supply in Australia is available on the [TGA website](#) along with the manufacturer's instructions for how to use the tests. This list is regularly updated as new tests are approved or if tests are cancelled or withdrawn.

Home use tests can be purchased on-line, from pharmacies or from any other retail outlet that stocks the test. Further information is available in the [consumer fact sheet \(pdf,393kb\)](#).

### What do the different brands of RAT tests mean?

The TGA's performance requirements for COVID-19 rapid antigen self-tests are internationally aligned with technical specifications published by the World Health Organisation (WHO) and the European Commission. This includes a clinical sensitivity of at least 80% (for specimens collected within 7 days of symptom onset) and a clinical specificity of at least 98%.

The table on the TGA [website](#) provides an indication of the performance of COVID-19 rapid antigen self-tests, including information on the clinical sensitivity of each test. This is based on the studies performed by the manufacturer which show the positive percent agreement (PPA). PPA is the proportion of individuals who tested positive to COVID-19 using a rapid antigen self-test, compared to those who tested positive to COVID-19 using a more sensitive PCR test.

The inclusion of this information does not represent TGA endorsement of a particular test as all approved tests meet the performance requirements. The manufacturer's sensitivity information is also included in the instructions provided with each test and can be viewed by clicking on the links in table below. For each test a comment on the clinical sensitivity is assigned as follows:

- **Acceptable sensitivity** - clinical sensitivity greater than 80% PPA
- **High sensitivity** - clinical sensitivity greater than 90% PPA
- **Very high sensitivity** - clinical sensitivity greater than 95% PPA

### Is it in multiple languages?

In relation to translated resources for rapid antigen tests (RAT), the guidance provided by the TGA outlines the requirements for instructions for use, including that they can be used by individuals of different literacy levels and be available in multiple languages. The inclusion of simple diagrams or pictograms providing step by step instructions also improves usability for users who speak a language other than English. The Therapeutic Goods Administration (TGA) have not enforced that Instructions for Use (IFU) must be provided in other languages, but it is encouraged. There is no requirement about videos in other languages.

Requirements to be met by sponsors (suppliers) of COVID-19 RATs vary, depending on whether the test is approved as a point-of-care test or a self-test.

Following the recent changes around use of rapid antigen test (RAT) self-tests and there no longer being a requirement for confirmatory PCR testing, the TGA has updated their [consumer fact sheet](#).

The requirements for labelling to be provided are detailed in the supporting data checklist at <https://www.tga.gov.au/sites/default/files/checklist-for-application-covid-19-rapid-antigen-self-test.docx>

All of the details in this checklist (including labelling requirements in the last appendix) are required to be met.

There is also more information on labelling in the TGA guidance document [COVID-19 rapid antigen self-tests – Performance requirements and risk mitigation strategies](#)

*Will there be other vaccinations that are able to given to children?*

Currently, the Comirnaty (Pfizer) paediatric COVID-19 vaccine is approved in Australia for children aged 5 to 11 years and the and the Spikevax (Moderna) COVID-19 vaccine for children aged 6 to 11 years. Information about COVID-19 vaccines for children is available on the Department of Health website: <https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/who-can-get-vaccinated/children>

No COVID-19 vaccine is currently approved in Australia for children aged under 5 years. The TGA has not received an application to extend the use of any provisionally approved COVID-19 vaccine to children under 5 years of age. Once an application is received to register a vaccine for use in this age group, it will be evaluated by the TGA with the greatest priority. There are clinical studies underway for children under 5 years of age. This includes clinical trials currently being undertaken by Pfizer to determine the appropriate dose for children under 5 years of age, as a lower dose than that approved for children aged 5-11 years may be required. The TGA is in regular contact with vaccine sponsors to ascertain their plans for future data submission, which includes outcomes of clinical trials in children under 5 years of age. If a vaccine for children under 5 years of age is registered for use by the TGA, the Department of Health will seek advice from ATAGI as appropriate. ATAGI will make its recommendations after carefully considering the relevant risks, benefits and uncertainties of the evidence.

*What health care is available should our clients on non-substantive visas/no visas become seriously unwell with COVID-19? For example, a provider is supporting a PNG single mother who is living undocumented in the community, she applied for a protection visa, but received a rejection letter from Home Affairs so technically is not able to prove asylum seeker status. I also have other clients of PNG background claiming TI ancestry who are undocumented.*

The network of 134 [GP-led Respiratory Clinics](#) (GPRCs) across Australia are funded by the Commonwealth to provide free medical assessments to people with respiratory symptoms, conduct testing where required and provide treatment services to COVID positive people. All services provided through GPRCs are available to people who do not hold a Medicare card.

The Department of Home Affairs and Department of Social Services have provisions in place to support asylum seekers access rapid antigen tests (RATs):

- The Department of Home Affairs will provide clients in Residence Determination with access to 10 free RATs from the Detention Health Service Provider (IHMS) pharmacies

over a 3-month period, based on the Department of Health advice for those with government-issued concession cards. This approach is consistent with community standards, on the basis of the inherent vulnerabilities of the Residence Determination cohort.

- The Department of Social Services oversees an Emergency Relief (ER) program. ER can provide assistance to people in financial crisis, including asylum seekers. ER services are delivered by 196 Commonwealth-funded community organisations nationally and help people address immediate basic needs in times of crisis. ER supports people experiencing financial distress or hardship and who have limited means or resources to help them alleviate their financial crisis. The type of assistance offered by ER providers may include food, clothing, vouchers, budgeting assistance, and referral to other services. This may also include support to purchase a rapid antigen test (RAT), where there are no other options available. Access to ER is free. There are no citizenship or residency requirements to access ER. People seeking assistance can access contact details for ER providers by selecting 'Financial Crisis and Material Aid - Emergency Relief' on the DSS Grants Service Directory at <https://serviceproviders.dss.gov.au/>. Ask Izzy is also a free resource for people to find other support services close to them.

*Are there multilingual resources available to support with helping clients access their vaccine certificate?*

The Services Australia website has [information about getting proof of COVID-19 vaccination](#), including how to get proof when you don't have Medicare or can't have a COVID-19 vaccination for medical reasons. Services Australia has also published [Easy Read resources](#) about getting proof of COVID-19 vaccinations.

*ATAGI recommends you wait 3 months from time of COVID infection before having your third vaccination. Is the same time frame if a child is COVID positive and has only had one vaccination? Information is coming out of Canada says there may not be as much protection from COVID antibodies as once thought and getting vaccinations earlier than three months may be better. Is there a comment. I appreciate this is an area of constant change.*

Past SARS-CoV-2 infection is not a contraindication to vaccination and people who have had COVID-19 should receive the same number of COVID-19 vaccine doses as people who have never been infected. People with SARS-CoV-2 infection can be vaccinated when they have recovered following their confirmed infection, or can defer for up to 4 months after the onset of the infection (with or without symptoms).

- There is no minimum timeframe.
- The advice is the same no matter the age of the person.

ATAGI recently decreased the timeframe from 6 months to 4 months based on the increased risk of re-infection with the Omicron variant, particularly for those who had a Delta variant infection in 2021.

- Previously, past infection was shown to reduce the risk of reinfection for at least 6 months.
- However, early evidence from the Omicron wave shows there is an increased risk of re-infection that was not present during the Beta and Delta variant waves.

*There are large groups of clients who had attended vaccine hubs through the support of service providers and have been unable to get their vaccination certificate due to their records going missing. In other cases, records have been made under different names, or the client's name on their Medicare account and their myGov account is different, so the two can't be matched. This is causing service providers to spend a lot of time trying to resolve these issues. In addition, due to the inability of these clients to get their vaccine certificate, there are many clients who have hesitated in getting their booster vaccines, or to get their children vaccinated.*