COVID-19 Rapid Antigen Testing in asymptomatic people

- The Abbott Panbio™ Rapid Antigen test (RAT) is the selected point of care test for testing asymptomatic, unvaccinated people >12y to enable travel
- RATs will be undertaken by selected community pharmacies Dec-Jan 22
- Abbott Panbio™ report a sensitivity of 91% and specificity of 99%
- Evidence in asymptomatic populations is limited; current data in *this* population show sensitivity of 50-58%[1-3], specificity is high at 99%

Consideration when using RATs as a screening test

- Even a high-performing RAT when used in very low prevalence setting (like Canterbury at present) will have a low Positive Predictive Value[4]
  - Few people may test positive overall, and many of these may be false positives[4]
  - Confirmatory testing with a PCR is required to avoid unnecessary isolation
  - Nearly half of people who do have COVID-19 will return a negative test
- People who develop symptoms need to be reminded to isolate and get tested again, even if they have recently had a negative RAT

Clinical Quality and Education Team comment:
The use of RATs to detect COVID-19 is likely to increase. They are a useful tool for providing quick information and reducing the system demand for PCR testing. As with any test, there is a chance of both true or false positive and negative results. It is important all health professionals understand the predicted test performance in the populations using these tests to be able to have informed discussions with patients. As the prevalence of COVID-19 changes, so will the positive predictive value.

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Background

Under the COVID-19 protection framework from the 15th December 2021 asymptomatic unvaccinated people >12yo who are travelling domestically with a transport company are required to carry evidence of a negative test result no more than 72 hours prior to travel (this includes those who are not fully vaccinated, i.e. only had a single vaccine).

The Ministry of Health has made available the Abbott Panbio™ Rapid Antigen test for COVID-19 screening by trained community pharmacists. They are to be used to:

- Support unvaccinated people to travel safely within New Zealand
- Reduce number of people with undiagnosed COVID-19 infection travelling
- Reduce the polymerase chain reaction test (PCR) testing load on laboratories

If a person tests positive they must immediately self-isolate and get a PCR test to confirm the diagnosis.[5] A PCR test is a highly accurate laboratory test that shows if a person is currently infected with COVID-19. PCR tests may use either nasal/throat or saliva samples.[5]

Recap of Sensitivity, specificity, and predictive values

Sensitivity, specificity, positive and negative predictive value are important concepts in testing.

- **Sensitivity**: The proportion of people with the condition who return a positive test
- **Specificity**: The proportion of people who don't have the condition who return a negative test
- **Positive predictive value** (PPV): The proportion of people with a positive test who actually have the condition
- **Negative predictive value** (NPV): The proportion of people with a negative test who truly do not have the condition
- **Prevalence**: the proportion of people in a population who have the condition at a given point in time

Sensitivity and specificity relate to the *test* itself; for a given disease and test, they stay the same, regardless of who is being tested.

However, PPV and NPV depend on sensitivity, specificity *AND* prevalence. For a given disease and test, they change depending on the prevalence in the population being tested.

RATs performance in relation to COVID-19 Sensitivity

- Abbott Panbio™ website lists the nasal swab RAT sensitivity and specificity as 91.1% and 99.7% respectively[6]
- WHO recommend RATs meet minimum performance requirements of ≥80% sensitivity and ≥97% specificity[7]
- A Cochrane review found in *asymptomatic* participants using a range of different RATs sensitivity of 58% (95% CI 40 to 74%) and specificity of 99% (95% CI 93 to 99%) (12 evaluations; 1581 samples, 295 cases)[1]
- A recent study specifically of the Abbott Panbio™ RAT in asymptomatic people, found sensitivity of 55%. The authors suggest they should not be used for ruling out COVID-19 in this population[3]

Positive and Negative Predictive Values

- As with any test, the PPV is lower when the test is used in low prevalence settings. The table below demonstrates this. At present COVID-19 prevalence in Canterbury is low, so the PPV will be low.
  - As prevalence increases the PPV improves
  - RATs may return a high number of false positives[4,7]
  - Travellers are expected to be a low prevalence population[7]

Table One

RAT performance			
Prevalence of COVID-19	Low (1:10,000)	Med (1:1000)	High (1:100)
PPV	0.6%	5.3%	35.9%
NPV	100%	99.9%	99.5%

(Assuming sensitivity 50% and specificity 99.1%[2])

Factors that Influence RAT Performance

Sample collection is critical to the test performance, it is optimal when performed by trained operators in accordance with manufacturer's instructions.[7] There are very specific instructions on timings and use of the reagents plus reading the results.[8]

Other factors in the clinical setting include:

- patient factors: e.g. immune status
- shipping, storage and shelf life of tests

Impacts of test outcomes

False positive test:

- The person will be directed to self-isolate and get a PCR test[4 5] ; however the PCR will show they will be uninfected
- They may subsequently miss their planned travel

False negative test:

- An infected person remains in the community and does not receive any care[4]
- People may be falsely reassured and wrongly attribute new symptoms to hayfever or a cold
  - People who return a negative RAT should be advised to isolate and seek a test if any symptoms develop

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