Briefing

Rapid antigen testing: Progress update and proposal for broader implementation

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To:	Hon Chris Hipkins, Minister for COVID-19 Response		

Contact for telephone discussion

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Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

Rapid antigen testing: Progress update and proposal for broader implementation

Security level:	IN CONFIDENCE	**Date:**	24 September 2021
To:	Hon Chris Hipkins, Minister for COVID-19 Response		

Purpose of report

1. This briefing provides you with advice on the use of rapid antigen testing. It provides an update on the Middlemore Laboratory rapid antigen testing pilot and the design of the point of arrival pilot.
2. This briefing seeks your agreement to prepare further advice to implement rapid antigen testing as part of outbreak management and to bolster community surveillance for COVID-19.

Summary

3. We propose to implement the use of rapid antigen testing in specific circumstances to strengthen the range of surveillance and testing options available. This supports the need to strengthen public health settings as part of the Reconnecting New Zealanders work programme.
4. Rapid antigen testing is faster than other testing options available currently, and there is a good evidence base to inform more detailed consideration of its use. The evidence base on the efficacy for use in different settings and by different health workers and people in the community continues to evolve.
5. There are potential uses for rapid antigen testing in high prevalence settings when a positive result is likely to be a true infection, and in low prevalence settings where there is a benefit to identify those who are highly infectious, including screening asymptomatic cases in workplaces, education settings and in the community.
6. We are exploring how we can effectively use rapid antigen testing and point of care rapid antigen testing in appropriate settings, including through two specific trials.
7. The Middlemore (CMDHB) diagnostic laboratory is currently overseeing the development of a pilot at the emergency department at Middlemore Hospital. The evaluation of the pilot will help us define the potential utility in health care settings.
8. The Ministry of Health is also leading the development of a pilot for point of arrival settings for people who are part of the self-isolation pilot at the border (as part of the Reconnecting New Zealanders work). This will inform ongoing work around rapid testing approaches for border risk management and inform the proposed implementation strategy.

9. We will provide you with an update on the pilot evaluation sites at the end of October 2021. We will also provide you with further advice on the proposed implementation alongside this update.

10. We have also sought further advice on the wide use of rapid antigen testing from the Testing Technical Advisory Group, chaired by Professor David Murdoch. The group is working at pace, and we expect to provide further advice to you in the week commencing 4 October 2021.

Recommendations

We recommend you:

a) **Note** that there is emerging evidence to support the use of rapid antigen testing in a range of settings where an immediate result allows quick decision making about infectious risk — **Noted** ✓

b) **Note** that Middlemore diagnostic laboratory is currently implementing a pilot of rapid antigen testing in the Middlemore Hospital emergency department. — **Noted** ✓

c) **Note** that we are currently leading the design of a pilot to use rapid antigen testing at point of arrival for participants in the self-isolation pilot to inform decisions around border management — **Noted** ✓

d) **Note** that these pilots and further research and experiences in other countries will all help inform the potential broader application of rapid antigen testing — **Noted** ✓

e) **Note** that we have sought further advice on rapid antigen testing from the Testing Technical Advisory Group and will provide further advice on the week commencing 4 October 2021 — **Noted** ✓

f) **Agree** that we will provide you with an update on progress with pilots at Middlemore and at the point of arrival at the end of October 2021 — **Yes/ No**

g) **Agree** that officials will provide further advice on the proposed implementation approach by the end of October 2021. — **Yes/ No**

Dr Ashley Bloomfield
Director-General of Health
Te Tumu Whakarae mō te Hauora
Date:

Hon Chris Hipkins
Minister for COVID-19 Response
Date: 28/9/2021

I remain concerned that this work lacks urgency. Please make sure that we are in a position to move quickly at the end of the trials (eg. MedSafe approval process should be already underway etc not wait till further down the track).

Rapid antigen testing: Progress update and proposal for broader implementation

Background and context

1. Rapid antigen tests detect specific proteins on the outside of the SARS CoV-2 virus, such as the spike protein. This method requires a much higher quantity of the virus to be present in the sample. As a result, antigen tests tend to be less sensitive at detecting cases, especially in asymptomatic persons or people who are either very early in, or towards the end of their infectious period.

2. Rapid antigen testing sits within a broader context of the range of tests currently being used in New Zealand for the diagnosis of SARS CoV-2 infection, and a summary of these testing technologies is provided in Appendix 1.

3. We are exploring how we can effectively use rapid antigen testing and point of care rapid antigen testing in appropriate settings, and this has the potential to support outcomes sought through *Aotearoa New Zealand's COVID-19 Surveillance Strategy*.

4. The advantage of antigen tests is that they are relatively cheap to perform and have a much quicker turnaround time for results than RT-PCR (Reverse Transcription Polymerase Chain Reaction) testing.

5. Rapid antigen testing can provide a result within 15-30 minutes. This is faster than the current gold standard rapid protocol RT-PCR test which can take at least 90 minutes. Non-rapid analysis by RT-PCR usually takes 4-6 hours.

6. This fast turnaround has the potential to provide more timely information in situations where it is advantageous for rapid risk assessment and related decisions. Potential settings where this may be required include where high numbers of people need to be tested and the results are needed quickly to, for example, make a decision for the person to cross a border or for essential workers during an outbreak.

7. So far, rapid antigen testing has required the sample to be from a nasopharyngeal swab or anterior nares swabs, as that is where we will find a lot of antigen. However, there are developments coming that may see alternative sample options such as saliva.

8. Rapid antigen testing can be conducted in a laboratory, a health setting, or in the community e.g., at home. A point of care rapid antigen test is one that is performed at or near the place where a specimen is collected and interpreted usually under the supervision of a health care professional eg, GP clinics, pharmacies, school health clinics, long term care facilities.

9. We have previously provided advice about the use of rapid antigen testing alongside rapid RT-PCR testing as part of a rapid testing trial for passengers at the point of arrival [HR20211972 refers]. This trial is intended to support a risk-based approach to entry pathways as part of the Reconnecting New Zealanders work programme. Surveillance is also a crucial element supporting the Elimination Strategy and maintaining strong public health settings.

Evidence base for rapid antigen testing

How is rapid antigen testing used within the current surveillance context

10. Rapid antigen testing is currently only permitted for pre-departure testing for incoming travellers, and in specific pilot evaluation settings. There is potential in the future to use rapid antigen testing in potential outbreak scenarios to test many people quickly. It could also be used for testing returning travellers to rapidly test and triage.

11. In Appendix 2 you will find more detail on the evidence for rapid antigen testing and information on its use in Singapore and Australia. In summary, the advantages and disadvantages of rapid antigen testing are as follows:

Table 1: Advantages of rapid antigen testing compared to other forms of testing

Advantages	Disadvantages
The rapid antigen test is a much quicker test than other options which can return a result in 15-30 minutes (compared to 90 minutes in the fastest case for rapid RT-PCR tests)	The sensitivity (the ability of a test to correctly identify a disease) of rapid antigen tests are generally lower (average sensitivity 68.9%[1]) for detecting people with COVID-19, particularly compared to RT-PCR tests.
Can be used to supplement RT-PCR testing of nasal or saliva swabs in high prevalence situations, and when speed of use and the faster result outweigh the risk of false negative results.	Need to be supplemented by RT-PCR testing, particularly in low prevalence situations.
Cheaper and easier to process, particularly as they can be processed in community settings.	Will require training and support for use in the community and additional workforce capacity and other systems to administer the tests and provide associated support in healthcare settings.

12. We will continue to engage with the emerging research base to inform implementation considerations.

Pilots at Middlemore Hospital and point of arrival will inform the evidence base

13. The Middlemore laboratory is implementing a rapid antigen testing pilot for the testing of patients presenting to the emergency department at Middlemore Hospital. An update on the work underway is attached in Appendix 3. This will be going live once training and local validation of the tests has occurred, likely commencing in the week of 4 October 2021.

14. The intent of this pilot is to prevent the spread of COVID-19 by patients being seen and admitted through the emergency department, and to test the utility and effectiveness of

[1] **average of sixteen different assays (https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013705.pub2/full)**

rapid antigen testing as a triaging tool in a high-risk setting. It will also inform consideration of future workforce needs, IT infrastructure requirements, and the patient experience. Depending on the outcomes of the pilot, this could prove effective for use in other hospital and health care settings.

15. The Ministry of Health is also leading work on the design of point of arrival testing for participants in the self-isolation pilot. The design is being undertaken in collaboration with the Border Executive Board's Future Borders and Self Isolation workstreams as part of Reconnecting New Zealanders. We have committed to trial this approach between October and December 2021 alongside the self-isolation pilot. An update on the implementation timeframes and how the pilot will operate is attached as Appendix 4.

16. The pilot is being used to test the efficacy of different tests in point of arrival settings as part of border management risk assessment. This will inform future decisions around self-isolation and the role of various tests in border management more broadly, particularly for entrants to New Zealand through the proposed medium-risk pathway. It will also inform associated operational requirements and logistics.

17. We will update you on progress with both of these pilots at the end of October 2021.

The tests for these pilots are being provided by the Ministry of Health

18. The testing kits for these pilots are being provided through a Ministry of Health (the Ministry) supply. In accordance with the requirements of the COVID-19 Public Health Response (Point-of care Tests) Order 2021, the Director-General of Health has approved the Ministry to import and distribute three rapid antigen tests to approved entities; and the tests are listed in Table 2 below. These kits were selected based on the evaluation that was completed by Institute for Environmental Science and Research (ESR) and Auckland LabPlus, which considered technical performance as well as ease of use. You will find more detail on the outcomes of the evaluation in Appendix 5.

Table 2: Testing kit availability and their intended uses.

Kit	Number sourced	Arrival date	Specifications	Administration	Intended use of Ministry of Health supply
Carestart COVID-19 Antigen test	100K	Arrived Auckland 15/9/21	Nasal swab samples; result read at 10 minutes	Samples can be collected by trained healthcare professionals or individuals can perform sample self-collection with a nasal swab, supervised by a trained professional.	For initial use in controlled pilots associated with testing as part of the public health response. eg ED patients at Middlemore Hospital; point of arrival testing pilot
SARS-CoV-2 Rapid Antigen Test Nasal (SD Biosensor)	100K	End of September	Nasal swab samples; result read at 15 to 30 minutes		
Panbio COVID-19 Ag Nasal	100K	End of September	Nasal swab samples; result read at 15 to 30 minutes		

Implementation considerations

Rapid antigen testing can enhance our current suite of testing options if used in the right settings.

19. In addition to the potential use of rapid antigen testing in border and hospital settings, we are considering potential uses in the community.

20. The use of rapid antigen tests is appropriate in high prevalence settings when a positive result is likely to indicate true infection, as well as in low prevalence settings to rapidly identify highly infectious cases. Rapid antigen tests can help reduce further transmission through early detection of highly infectious cases, enabling a rapid start of contact tracing and isolation.

21. Situations where the use of rapid antigen tests may be appropriate include:

    a. high prevalence settings when a positive result is likely to be a true infection, eg border settings

    b. low prevalence settings where there is a benefit to identifying those who are highly infectious and enabling rapid contact tracing eg for testing essential workforces or schools where there is a need for frequent, repeated, and widespread testing of groups of people and/or there is a need for rapid results eg during an outbreak.

22. If a person is symptomatic or a contact of someone with COVID-19 then it is more appropriate to use a RT-PCR test.

23. There will need to be careful consideration of the consequences of introducing rapid antigen testing under any scenario, including how to mitigate any potential adverse impacts of false negative test results where the risk arises because a person does not know they are infectious.

Implementation considerations

24. A wider roll-out of rapid antigen testing in health care and/or community-based settings will require significant planning, and given the complexities and risks, it will need to be underpinned by a strong implementation strategy in coming weeks. The strategy will need to consider both health care settings and community settings and identify priority areas for roll-out. The timing will allow us to learn from the Middlemore Hospital pilot to inform the implementation strategy.

25. Implementation issues that will need to be addressed for health care and community settings include:

    a. the approvals process, and whether we would look to approve any more tests than the three that are currently approved. Utilising three different tests has the benefit of having different options in case supply issues emerge. However, it is likely that we would look to identify one test for each setting. This would make it easier to monitor implementation and manage issues with tests if they were to emerge.

    b. identifying the appropriate level of medical involvement in testing in different settings, including where the taking of the swab and the analysis of the test can be, at a minimum supervised by trained staff, or where both the swabbing and the testing will be undertaken by healthcare staff. In some community settings it may be deemed appropriate for individuals to self-administer a test. We will also be considering pharmacies as a potential testing site, as pharmacists are often trained in appropriate testing techniques.

c. health sector capacity to manage the supply of tests, and ensure that there is appropriate capacity to manage testing demands. It is likely that we would initially work with DHBs to oversee supply and the testing process. We will need to engage with the health sector to identify scale and phasing implications of the enhanced testing regime, as well as detailed considerations of settings that could be used during roll-out phases.

d. funding implications, in particular in what settings we might publicly fund and where we might look to private businesses or out of pocket payments.

e. if any restrictions need to be placed on privately sold tests.

f. how positive tests would be managed, and mitigations for the risk of false negatives. Where positive tests are identified, appropriate pathways will be required to inform Medical Officers of Health and reporting into EpiSurv public health surveillance system. In a low prevalence setting the biggest concern is false positive results[2] so as part of any further roll-out everyone with a positive rapid antigen test should have confirmatory RT-PCR test. Advice from other jurisdictions is that people with a negative rapid antigen testing should be vigilant in case they develop any symptoms and continue to observe all other public health recommendations including using masks and maintaining social distancing.

g. phasing of the roll-out, to manage potential constraints on supply of testing, time required to develop infrastructure, and to ensure that testing practice is based on evidence and evaluation.

h. regulatory requirements as changes are likely to be required to permit the sale and use of rapid antigen testing, particularly for tests without medical supervision. If this was to be progressed, we would need to change the current COVID-19 Public Health Response (Point-of-care Tests) Order 2021 under the COVID-19 Public Health Response Act 2020.

i. data collection and validation issues, particularly where testing is being used for travel and workplace settings. A number of the kits that are approved for use have QR codes and information-portals to capture results. We would need to develop agreements with vendors to connect with the Éclair clinical information system, for both local and international data-sharing.

26. Specific considerations would also be required to support the potential use in community settings, including:

a. the appropriate supply arrangements, including the management of the supply chain, and wholesale distribution of the tests. We would also need to work with healthcare logistics, primary suppliers, wholesale distributors and pharmacies to manage any limitations on access that might be required in community settings.

b. regulatory requirements, in addition to changes to adjust the Order to allow specific uses of the test. Medsafe advise that there are no pre-market requirements, but we would need to fulfil requirements should a recall be needed.

[2] **For example, assuming a prevalence of 1%, sensitivity of 80% and specificity of 95%, then if 10,000 people are tested there will be 575 positive results with 495 (86%) being false positive (see Table in Appendix 2)**

c. guidance to support the use of testing in community settings including workplaces and pharmacies, additional guidance would need to be developed to inform people of the appropriate settings to use the test, management of positives and the possibility of false positives, and data collection requirements where applicable.

d. an appropriate pricing structure, including consideration of whether special funding should be allocated for testing required for surveillance and to improve equity of access. It would also need to consider when and if user-pays arrangements can be implemented.

27. As part of work to design the implementation approach, we will need to work with the Testing Technical Advisory Group, New Zealand Point of Care Technical Advisory Group and the NZ Microbiology Network. We will also need to test our approach with Māori and Pacific leaders to ensure rapid antigen testing and associated communications are responsive to the needs of these communities.

28. We will also need to work with other agencies including the Ministry of Business, Innovation and Employment, and Worksafe to manage potential implications resulting from the use of rapid antigen testing in workplaces and other non-healthcare settings. This could include any regulations or guidance required to support the potential use of these tests in the workplace and addressing issues around privacy and consent.

Equity

29. The impacts of COVID-19 are felt differentially across New Zealand communities. Māori and Pacific communities and those living with disabilities, in lower socio-economic groups and crowded or institutional settings bear a greater portion of both health and economic impacts and risks. The surveillance and testing regime has been a key part of the response to prevent the outbreak or spread of COVID-19 to the community, particularly those communities with many workers in border settings or who are essential workers.

30. There is a higher proportion of Māori and Pacific individuals working at our borders when compared to the general population, and any changes to the testing regime will have a greater impact on this workforce. This impact will continue to be factored into the design and implementation of the wider testing programme.

31. Rapid antigen testing has the potential to expand access to testing, which in specific circumstances could be used effectively to meet community surveillance needs and provide greater assurance. Equity considerations will need to be considered during implementation, including not creating financial or other barriers to access.

Next steps

32. We will provide an update on point of arrival testing pilot and the Middlemore pilot by the end of October 2021.

33. Subject to your approval we will provide further advice on the proposed implementation of rapid antigen testing alongside the pilot update. This will be informed by the outcomes from the pilot sites, and the broader evidence based, as well as engagement with key stakeholders.

34. We have also sought further advice on the wide use of rapid antigen testing from the Testing Technical Advisory Group, chaired by Professor David Murdoch. The group is working at pace, and we expect to provide further advice to you in the week commencing 4 October 2021.

ENDS.

Appendix 1: Summary of SARS-CoV-2 testing technologies in New Zealand

Indication	Method	Primary intended use	Sample type(s)	Turnaround	Aotearoa New Zealand context
Current infection	RT-PCR	'Gold standard' diagnostic tool for confirming SARS-CoV-2 infection	Nasopharyngeal swab or saliva testing	1-2 days (rapid testing can take 90 minutes)	• Highly sensitive and specific and is used to confirm SARS-CoV-2 infection • Used as both a screening and diagnostic tool • Confirms any suspected case if another sample type was initially collected and is positive
		Screening programme or nasopharyngeal is not tolerated/ contraindicated	Nasopharyngeal swab, saliva, or combined nasal/throat	1-2 days	• Screening border personnel and incoming travellers • High frequency testing environments and high-risk individuals • Nasopharyngeal swab used to confirm a positive sample
	Antigen	Rapid diagnostic test. Not useful for ruling out cases	Nasopharyngeal swab, saliva, blood/finger prick	Mixed but can be rapid - less than 1 hour	• Only currently permitted for pre-departure testing Other proposed uses: • Rapid testing in potential outbreak scenarios to test many people quickly • Testing returning travellers as a way to rapidly test and triage
Past infection or immunity	Antibody (serology)	Confirm recent or past infection	Blood	1-2 days	• Determining historical cases that may have had a positive RT-PCR test result but is not symptomatic
		Seroprevalence	Blood	1-2 days	• Limited practical use in New Zealand with no circulating community transmission. Could be an option in the future to monitor disease burden
		Immunity from infection or vaccination	Blood	1-2 days	• Screen incoming travellers for proof of vaccination or confirm a person's immune state (when level of immunity has been well-established)
Public health surveillance	Genomic sequencing	Identify mutations and aid epidemiological investigations	Genetic material from positive samples	1-3 days	• Performed on every positive case in New Zealand. Not every positive case is able to be sequenced due to lack of viable genetic material or other sampling/testing issues
	RT-PCR	Community disease surveillance	Environmental sampling (treatment plants, sewage)	1-3 days	• Detection tool that complements other surveillance and testing strategies being implemented

Appendix 2: Detailed evidence on the use of rapid antigen testing, including overseas examples

Current evidence on rapid antigen testing

1. To date in New Zealand, we have relied heavily on the gold standard test RT-PCR (Reverse Transcription Polymerase Chain Reaction) performed on a nasopharyngeal swab sample. More recently this has been supplemented by RT-PCR performed on saliva samples. There is very limited capacity for further scaling of rapid RT-PCR testing, as this still takes at least 90 minutes to be processed in a lab (compared to the usual 24-48 hours), depending on laboratory capacity.

2. However, the rapid antigen test is a much quicker test which can return a result in 15-30 minutes. The better performing tests utilise a nasopharyngeal swab, oropharyngeal swab or a combined approach as a sample as this improves the chance that a high amount of virus appears for the test.

3. Generally, as a one-off test, rapid antigen tests have lower sensitivity (average sensitivity of 16 different assays was 68.9%, 95%CI: 61.8% to 75.1%) compared to RT-PCR. However, sensitivity varies with each brand of test. In addition, manufacturers of these tests tend to overestimate their test's performance. For example, the three rapid antigen tests evaluated by ESR showed a sensitivity of 30-35%; much lower than the reported sensitivity of 90% to 98% (Appendix 5). Sensitivity is also higher for people who are symptomatic, in the first week after symptom onset, and with high viral loads. Specificity (the ability of a test to correctly identify people without the disease) is generally high at over 95% (average over 16 assays was 99.6%, 95%CI: 99.0% to 99.8%).

4. Using a test with low sensitivity to detect cases of COVID-19 can increase the risk of transmission if those individuals are not isolated from the rest of the community due to the numbers of false negative results. One approach to compensate for the low sensitivity is to increase the frequency of testing. Increasing the frequency of rapid antigen testing to at least every three days can increase the overall sensitivity to >95%.

5. The proportion of false negative results will depend on the sensitivity of the test, for example, using a rapid antigen test with sensitivity of 35%, then 65% of all people with COVD-19 will have a negative result; a test with 80% sensitivity will result in 20% of those with the disease having a negative test result. Approaches to mitigate this risk may include conducting a confirmatory RT-PCR test if there is a high index of suspicion that the person has COVID-19 or advising the person physically distance and wear a mask and get another test if symptoms develop.

6. With regards to false positive results, despite the high specificity of antigen tests, false positive results will occur, especially when used in communities where the prevalence of infection is low. Taking an example with a prevalence of 1% and using a test with 80% sensitivity, if 10,000 people are tested there will be 575 positive results with 495 (86%) being false positive results. This increases to over 95% with a prevalence of 0.01% (**Error! Reference source not found.**). An approach to mitigate this problem would be to get a confirmatory RT-PCR test with a positive rapid antigen test result in low prevalence settings.

Table 1. Estimates of number of false negative and false positive results by prevalence and sensitivity

Prevalence	Sensitivity	Specificity	Number of people tested	Number people with COVID	Number of false negative results	Number of positive test results	Number of false positive results
10%	35%	95%	1,000	100	65	80	45
10%	80%	95%	1,000	100	20	125	45
1%	35%	95%	10,000	100	65	530	495
1%	80%	95%	10,000	100	20	575	495
0.01%	35%	95%	100,000	10	7	5,003	5,000
0.01%	80%	95%	100,000	10	2	5,008	5,000

How have other jurisdictions used rapid antigen testing?

7. Other jurisdictions have utilised rapid antigen testing effectively as part of their overall testing strategy. For example, Singapore is providing every household with rapid antigen self-testing kits for COVID-19. The rationale is that as Singapore becomes fully vaccinated, testing and tracing is becoming the chief line of defence in managing outbreaks. Individuals are instructed that if a householder has a positive test (or two invalid results) they are instructed to take a photograph of the kits with their identity document and go to a registered clinic for a RT-PCR test, and isolate until that test is reported. Individuals are instructed that, if the result is positive, they will be contacted by the health authorities.

8. Australia's Therapeutic Goods Administration (TGA) has approved a number of rapid antigen tests for use. So that they are appropriately used, and the results interpreted correctly, they can currently only be legally supplied under specific conditions. This includes the use by specified trained health practitioners and trained staff under their supervision to ensure a suitable health practitioner is available to provide immediate clinical advice and treatment if required. Earlier this month they released guidance, training requirements and a checklist for business who are considering using rapid antigen testing to ensure that testing is carefully managed and used appropriately. We will be considering Australia's work when developing our own implementation approach.

Appendix 3: Update on the trial of Rapid Antigen Testing for patient screening in Middlemore Hospital

Context

1. In the context of the current outbreak of COVID-19, an urgent clinical use scenario has been identified for use of rapid antigen testing. Rapid antigen testing has been identified as a potential mechanism to prevent the spread of COVID-19 by patients being seen and admitted through Emergency Department (ED) at Middlemore Hospital into other parts of the hospital.
2. The pilot will utilise tests from the Ministry's supply as part of a pilot to screen patients presenting to the ED. The intent of the pilot is to test the utility and effectiveness of rapid antigen testing as a triaging tool in a high risk setting. The pilot will also test the operational elements such as data capture, healthcare workforce and patient experience. The evidence from this pilot will inform the wider use of rapid antigen testing, particularly in other healthcare settings.
3. The benefit or otherwise of introducing a rapid antigen test to other admitting services, eg maternity, or health services for older people, would be informed by an evaluation. The current evaluation design and appropriate peer review is being finalised.

Clinical considerations for the pilot

4. The use of the rapid antigen tests will be overseen by the Middlemore (CMDHB) diagnostic laboratory who will complete local verification of the devices before commencing the pilot. The Director-General of Health has authorised use of the approved rapid antigen test kits for the Middlemore pilot.
5. The pilot will be activated following local verification, as part of the normal laboratory protocols. The antigen test would only be performed in parallel to the routine laboratory-based RT-PCR. The intent of the pilot is to test the utility and effectiveness of rapid antigen tests as a triaging tool in a high risk setting. The pilot will also test the operational elements such as data capture, healthcare workforce and patience experience.
6. The pilot will be carried out by trained CMDHB staff, under the supervision of the Middlemore diagnostic laboratory and the Point-of-Care Coordinator.
7. The laboratory will be responsible for control of stock, quality control of kits, and training of users. Trained staff may include non-laboratory-based health care workers.
8. There would be a number of controls to support accuracy of testing and maintain effectiveness as a trial:
    a. Rapid antigen tests will only be performed in parallel with routine laboratory-based RT-PCR testing in cases where the patient (or visitor accompanying a child) agrees to the collection of a bilateral anterior nasal swab being collected for rapid antigen tests after the routine nasopharyngeal swab (NPS) has been collected for testing by RT-PCR.
    b. The result from the nasopharyngeal RT-PCR test will continue to be used for direct laboratory notification and ultimate decisions around clinical management including Infection Prevention and Control (IPC) precautions within the hospital.

c. In the event of a positive rapid antigen test and a leaked, unsuitable or indeterminate result from the RT-PCR swab sample, a second NPS for RT-PCR will be arranged.

d. The addition of antigen information will be included in a local algorithm during periods when the rapid antigen testing was being evaluated or in use. This will guide decisions during the interval (usually 2-3 hours) between the result of the antigen test and result of the RT-PCR test.

e. The Microbiology Lab will be informed of any positive antigen test to expedite the swab RT-PCR result, ie test singly if the swab sample has already been included in a pool for rapid PCR.

f. The Duty Emergency Medicine Fellow/Consultant will be informed of any positive rapid antigen testing to ensure correct IPC precautions are in place until the RT-PCR result is available. ED medical staff are prepared for the reality that there will be false negative and false positive antigen results. One of the purposes of the pilot is to see how often these occur and evaluate their impact.

9. Before commencing the pilot, we will confirm with Auckland Regional Public Health Service (ARPHS) whether they would act on a positive rapid antigen testing result or would wait for the confirmatory RT-PCR.

10. Results from the rapid antigen testing will be recorded in the regional Éclair system. This may require manually uploading results but methods to streamline or automate data collection will be explored as part of the pilot.

Appendix 4: Point of arrival testing pilot timeframes

Background

1. On 19 August 2021, the Ministry of Health (the Ministry) provided you with a report proposing a three-stage process for introducing point of arrival testing for COVID-19. The three stages were a small-scale controlled trial (pilot), a wider trial and then a phased roll out of point of arrival testing, with a phased roll out dependent on the findings of the pilot and trial [HR20211184 refers]. The report recommended two COVID-19 testing methods be piloted in stage one – Rapid Antigen Testing (RAT) and rapid reverse transcription polymerase chain reaction (rapid RT-PCR). The testing performed in the initial pilot would be in addition to current managed isolation and quarantine requirements.
2. You agreed to the Ministry putting forward a proposal to prepare for the establishment of a small-scale pilot of two COVID-19 testing methods at point of arrival into New Zealand and asked that it include a clearer timeline for implementation of the trial [HR20211814].

Objectives of the point of arrival testing pilot

3. The objective of the pilot is to determine the operational requirements, logistics and time required to take samples and perform rapid testing at the point of arrival into New Zealand, using one of the two testing methods identified as feasible in this context. The findings of the pilot are likely to be of most relevance for entrants travelling to New Zealand through the medium-risk pathway under the Reconnecting New Zealand framework and may contribute information to decisions about what kind of quarantine a person is required to undergo.
4. The point of arrival testing pilot is not independent of the pre-arrival and post-arrival processes that occur for medium-risk passengers entering New Zealand, including disembarking, passing through the airport and then on to MIQF or self-isolation (as part of the proposed pilot), and so needs to align with those processes.
5. The Ministry has been working with other agencies, to identify how the point of arrival trial interfaces with the Reconnecting New Zealand and Border Executive Board Future Borders work programmes to ensure alignment.
6. Cabinet has agreed to run a pilot of self-isolation that will test some of the systems and processes for a medium-risk pathway in advance of substantive policy decisions on medium-risk entry pathways in 2022 [CAB-21-MIN 0305].
7. Further detailed discussions are required with the relevant operational leads at the intended pilot site/s, including Airport, Customs, local district health board (DHB) and laboratory leads to work through the complex implementation issues. The point of arrival testing pilot will provide useful information on the operational feasibility of point of arrival testing and where and how that best occurs.

Participant selection

8. The Ministry has identified an opportunity to use all or a subset of participants in the self-isolation pilot to also pilot point of arrival testing, which would be the first test in the series of tests a person will undergo over the 14 days they are in self-isolation. Note,

however, that this will not test the logistics of doing point of arrival at scale in the airport, with whole plane loads of people.

9. Point of arrival pilot participants will therefore be fully vaccinated New Zealand citizens and residents who have been fully vaccinated in New Zealand with Cominarty (Pfizer-BioTNech COVID-19 vaccine). In order to participate in the self-isolation pilot, participants must comply with all testing requirements set out by the Ministry, therefore compliance with point of arrival testing will be adhered to.

10. The use of this pilot will inform the wider reconnection approach for New Zealanders and contribute to further the availability of safe international travel for all New Zealanders in the future.

Proposed process for the point of arrival testing pilot

11. Point of arrival testing process includes collection of two samples by or under supervision of a healthcare worker; one (anterior nasal swab) for the rapid antigen test and a second (nasopharyngeal swab) to be sent to the laboratory for PCR testing. This will allow verification of the results of the rapid antigen tests and further support the assessment of the accuracy of the tests at point of arrival. This test will represent the "day 0" for this pilot cohort.

12. Rapid antigen testing can typically take 15-30 minutes. However, the end-to-end process could take up to 1.5 hours when you take into consideration time taken to inform the participant of the process, confirm identification, collect and capture person's details, take multiple swabs, complete the analysis and capture results in the information system used. It is anticipated that the pilot participants will not be required to wait in the airport for the results, as they will be transiting into a self-isolation dwelling. Results will be entered into the laboratory system and reported through as per normal laboratory reporting protocols.

13. The second sample taken for laboratory PCR will be sent to the local testing laboratory and undergo normal testing protocols. Test results will be reported as per normal laboratory reporting protocols.

14. For this pilot, all results will be reconciled with the laboratory PCR results, where the trigger for action will be driven by the laboratory PCR test result.

15. The use of rapid RT-PCR testing is currently in place through the laboratory testing network. A variety of platforms are utilised and typically results are available within 1.5 hours from when samples are collected. For this pilot, current operational data will be used to report back on the functional use in a point of arrival scenario. There are limitations on scalability and only a limited number of platforms available that can provide high throughput testing (up to 80 samples per run per machine), but none of which are currently available or implemented in New Zealand.

Proposed dates for the point of arrival testing pilot

16. The Ministry is aware that a Cabinet paper setting out the high-level design and indicative time frames for the self-isolation pilot was considered by the Cabinet Social Wellbeing Committee on 22 September and will be considered by Cabinet on 27 September 2021. This work is being led by the Ministry of Business, Innovation and Employment and will commence with an Expressions of Interest (EOI) process for people wanting to participate.

17. The indicative timeframes for the self-isolation pilot, which are subject to change, and will not be finalised until completion of the pilot design, are as follows:

EOI process goes live	30 September
EOI process closes	9 October
Participants confirmed	14 October
Arrival window opens	30 October
Final arrivals in New Zealand	8 December
Final travellers exit self-isolation	22 December

18. Point of arrival testing will therefore operate from approximately 30 October to 8 December 2021.

19. The Ministry is confident that the point of arrival testing pilot can align with the self-isolation pilot time frames and will be able to adapt to any changes to this schedule.

Appendix 5: Review of Rapid Antigen Testing Technologies

Test manufacturer	Assay type	Acceptable sample types	Professional or self-collected	Processing location	Read time	FDA (US), TGA (AUS), Singapore approval	Manufacturer sensitivity (Sn) and specificity (Sp)*	ESR reported sensitivity and specificity**
AccessBio CareStart	Lateral flow	Anterior Nares or Nasopharyngeal	Either	Non-lab	10 min	FDA, TGA	AN: Sn 87.2%, Sp 100% NP: Sn 93.8 %, Sp 99.3%	Overall Sn 31.6% (95%CI: 19.0% to 47.6%) Ct <25: 100%
Abbott Panbio	Lateral flow	Anterior Nares or Nasopharyngeal	Either	Non-lab	15 min	TGA, Singapore authorised self-test kit	AN: Sn 98.1% (99.0% for samples with Ct values ≤ 33), Sp 99.8% NP: Sn 91.4% (94.1% for samples with Ct values ≤ 33), Sp 99.8%	Overall Sn: 34.2% (95%CI: 21.2% to 50.2%) Sn Ct <25: 100%
SD Biosensor SARS-CoV-2 Antigen	Lateral flow	Anterior Nares or Nasopharyngeal	Either	Non-lab	15-30 min	TGA, Singapore authorised self-test kit	Sn 95.5% (Ct Value ≤ 30), Sp 99.2%	Overall Sn: 34.2% (95%CI: 21.2% to 50.2%) Ct <25: 100%
Quidel QuickVue At-Home OTC COVID-19 Test	Lateral flow	Anterior Nares	Self-collected	Non-lab	10 min	FDA, Singapore authorised self-test kit	Sn 83.5%, Sp 99.2%	Not tested
SD Biosensor Standard Q COVID-19 Ag Home Test	Lateral flow	Nasopharyngeal	Medical professional use	Non-lab	15-30 min	TGA, Singapore authorised self-test kit	Sn Ct ≤ 25: 97.14%, Ct ≤ 33: 90.71%, overall: 84.97% Sp 98.94%	Not tested
BD Veritor At-Home COVID-19 Test	Lateral flow	Anterior Nares	Self-collected	Non-lab	15 min	FDA, TGA, Singapore authorised self-test kit	Sn 81%, Sp 100%	Not tested
BD Kit for Rapid Detection of SARS-CoV-2	Lateral flow	Anterior Nares	Self-collected	Non-lab	15 min	Singapore authorised self-test kit	Unable to locate	Not tested

*Manufacturer performance almost always universally overstated and requires proper in-field testing. Science and Technical Advisory has not been able to fully evaluate and thoroughly research published literature on the performance of RAT in this document due to time constraints.

** The Institute of Environmental Science and Research (ESR), Review of Point-of-care antibody and antigen rapid diagnostic tests for COVID-19. 2021, ESR: Porirua, New Zealand.