## Briefing

## **Testing Options at Point of Arrival**

Date due to MO:	19 August 2021	Action required by:	20 August 2021								
Security level:	IN CONFIDENCE	Health Report number:	: HR20211814								
То:	Hon Chris Hipkins, Minis	ter for COVID-19 Response									
Contact for telephone discussion											
Name	Position		Telephone								
Bridget White	Deputy Chief E System Respor	ixecutive – COVID-19 Health nse	s 9(2)(a)								
Darryl Carpenter	Group Manager – Testing and Supply s 9(2)(a)										
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Minister's office to complete:											
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Comment:											

## **Testing Options at Point of Arrival**

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

#### **Purpose of report**

This briefing explores how point of arrival testing for SARS-CoV-2 can be established, to 1. support New Zealand to maintain its Elimination Strategy while gradually re-opening its borders. This report discloses all relevant information.

#### Summary

- 2. This briefing builds on the Cabinet Paper entitled, "Reconnecting New Zealanders with the World: Shifting to a Risk-Based Approach to Border Settings." It explores how point of arrival testing can be used to support the three arrival pathways set out in the Cabinet Paper. [CAB-21-MIN-0305 refers]
- This briefing includes a table summarising the different methods of testing for SARS-3. CoV-2 and outlines their suitability for point of arrival testing, including considerations required to operationalise the two recommended options.
- Next steps to outline what would be required to develop a small-scale, controlled trial of 4. the two recommended point of arrival testing options are set out.

#### **Recommendations**

We recommend you:

- Note that a range of COVID-19 testing methods have been reviewed and Yes/No a) considered for possible use for point of arrival testing.
- **Note** that it is currently the Ministry's view that point of arrival testing will **Yes/No** b) most likely be relevant for 'medium-risk' entrants, pending further exploration.
- Note the resources that will be required to establish a small-scale, controlled Yes/lo c) trial of two of the testing methods outlined.
- d) Agree that a proposal is put forward to prepare for the establishment of a Yes/No small-scale, controlled trial of two of the testing methods discussed, trained healthcare worker administered rapid antigen and rapid RT-PCR testing.

**Bridget White Deputy Chief Executive** 

**COVID-19 Health System Response** Date:

Hon Chris Hipkins **Minister for COVID-19 Response** Date: 26/2/21

I would like b see a clearer fineline to the trial and possible implementation. This needs a greater sense of vrgmmy. all







# **Testing Options at Point of Arrival**

### Background

- 5. There are several testing methods and sample types which have been used in New Zealand and overseas to test for SARS-CoV-2, the virus that causes COVID-19. Since the beginning of the COVID-19 response, a method of nucleic acid amplification testing (NAAT) called reverse transcription polymerase chain reaction (RT-PCR) has been firmly established in the diagnostic laboratories performing testing as part of the public health response. This is the gold standard for testing for SARS-CoV-2. In addition to high throughput laboratory based NAAT methods, low throughput rapid NAAT platforms are currently also in use in New Zealand.
- 6. Another form of testing, which has not to date been used in New Zealand as part of the COVID-19 response is antigen testing. These tests detect specific parts on the outside of the SARS-CoV-2 virus, such as the spike protein. Antigen tests use antibodies from an analytical reagent that bind to antigens in a sample. When enough antigens and antibodies bind, this can be detected.
- 7. Rapid antigen tests (RATs) are performed on swab samples collected either by a healthcare worker or by the test recipient. The New Zealand Microbiology Network has strongly recommended any use of RAT be considered only as an addition to the current NAAT in place, not as a replacement.
- 8. Concern about the efficacy of these tests, based on international experience, has led to the restriction of the importation, and use of point of care (those conducted at the point where the sample is collected) rapid antigen tests in New Zealand unless authorised by the Director General of Health. As of July 2021, no point of care antigen testing kits have been approved for import and use in New Zealand. Approximately five RAT kits, using swabs as the sample type, have already been evaluated by ESR and LabPlus.

## What's happening internationally at the border

- 9. A variety of testing strategies exist in other countries. Many of these focus on predeparture PCR tests that must be completed before a journey begins. Many countries also have self or managed isolation requirements that include a series of tests that must be completed before isolation can end. Some countries are known to also utilise testing at the point of arrival, including Hong Kong and Singapore.
- 10. In Hong Kong, entrants arriving at Hong Kong International Airport are required to undergo testing immediately upon arrival and to wait in the airport for their results (approximately 2 to 3 hours).
- 11. In Singapore, all travellers (born in or before 2018) must take a Covid-19 PCR test upon arrival in Singapore but can leave the airport and receive their result by phone. Travellers from very high-risk countries/regions must undergo an on-arrival RAT, in addition to PCR tests.

### Point of arrival testing options

#### Arrival pathways

- 12. At present New Zealand operates two arrival pathways, being low and high-risk pathways. There are and have previously been travel 'bubbles' with a small number of low-risk countries, which grant entry without the need to isolate. For all other countries from which travel is permitted, a system of managed isolation for 14 or more days is operated, with anyone who tests positive for COVID-19 being moved to a managed quarantine facility.
- 13. It is anticipated that, with increased levels of vaccination in place, New Zealand will shift instead to three, risk-based entry pathways that are likely to incorporate vaccination, testing and isolation requirements in proportion to risk. The determination of risk will be based on an individual's travel history in the last 14 days. It is expected that point of arrival testing is likely to be of most relevance for entrants through the medium risk entry pathway and particularly those due to go into self-isolation. For entrants who plan to isolate in a managed facility, the best site for testing may continue to be the isolation facility where Day 0 or 1 testing has become routine.
- 14. Pre-departure testing and the testing that takes place during the period of isolation that follows arrival are two important considerations not explored in this briefing.

#### Options for testing methods and their suitability for point of arrival testing

- 15. There are many methods which have been used in New Zealand and overseas to test for SARS-CoV-2. While most of these are validated testing methods, they are not relevant in a point of arrival context. An example is whole genome sequencing, which is performed on samples for cases that have been determined to be positive. Antibody testing is not a relevant point of arrival test in the context of an elimination strategy as it does not detect the presence of the virus.
- 16. Four possible testing options have been considered for use at the point of arrival, which can detect the SARS-CoV-2 and be performed rapidly (in less than two hours). The table in Appendix 1 summarises these four testing methods. It outlines the types of testing and samples used and includes commentary on the availability of these tests in New Zealand and the sensitivity of the tests.
- 17. Two testing options have been discounted. The self-administered RAT is the least sensitive method considered, and due to both the nature of the test and how the tests would be conducted, it is advised that this is not a suitable option for point of arrival testing in New Zealand. Additionally, RT-LAMP was discounted as the resources required to operationalise it as a high throughput rapid test are similar to that of RT-PCR testing, but it has a lower sensitivity.
- 18. The trained healthcare worker administered RAT would take a little longer to establish due to training requirements but would be more sensitive. It is, however, expected that this testing method would fail to identify a significant proportion of positive cases, presenting significant risk where individuals are permitted to proceed from the airport to an unsupervised, self-isolation arrangement.
- 19. Rapid NAAT is the most sensitive test and would produce the most reliable results but would take considerable time and resources to set up as a high throughput rapid test. In

addition to the wait time for delivery and implementation of one or more high throughput platforms, a laboratory-like space would need to be commissioned at, or close to, the point of arrival testing site, to meet accreditation standards.

20. In summary, the two testing options recommended for further exploration are healthcare worker administered RAT and rapid RT-PCR. For these two options, next steps for a three-stage process to introduce point of arrival testing are discussed below.

### Equity

21. For the purposes of this briefing, it is anticipated that the cost of testing would be met by public funding and not by entrants.

### Suggested approach for piloting point of arrival testing options

- 22. A three-stage process for introducing point of arrival testing is proposed. These three stages would be a small-scale controlled trial, a wider trial and then a phased roll out of point of arrival testing.
- 23. To begin with, it is proposed that this briefing be used to inform the establishment of a small-scale, controlled trial to evaluate the two recommended testing options. This would provide additional evidence to determine the level of suitability of these two testing methods, which could inform a further, more fully formed trial to be conducted prior to implementation.
- 24. The testing performed in the initial trials would be in addition to current managed isolation and quarantine requirements.
- 25. To facilitate a trial using rapid antigen tests, a review of available point of care rapid antigen test kits would need to be performed ahead of selecting one or more test kits to trial. It is also noted that section 11 of the COVID-19 Public Health Response Act 2020 restricts importation and use of point of care Antigen kits unless authorised by the Director General of Health. Training in the use of these kits will be required once the kits are available.
- 26. For the rapid NAAT testing, a laboratory-like environment would need to be established at or near to a point of arrival, most likely at Auckland International Airport, and all the necessary equipment brought in, set up and validated to meet accreditation standards. For a small-scale trial, a number of lower throughput analysers could be used, which may be available more quickly than the high throughput analysers that would ultimately be required to efficiently process testing for a plane load of passengers.
- 27. For both recommended testing options, the space, staffing and logistics at the point of arrival will need to be discussed with relevant agencies and other key stakeholders.

#### Next steps

28. Following action in response to this briefing, a further briefing will be prepared by the end of August to describe in more specific detail how testing will be conducted as part of an initial, small-scale trial of the two recommended testing options outlined.

ENDS.

Testing Modality	Festimate of end to end TA (from sample being taken to result being available/reported)	T Sensitivity - Single Test relative to RT- PCR	Sample Type	Person collecting sample	Analysis Workforce	Where utilised in NZ	-ve Result Action	+ve Result Action	Considerations	Risks	Estimated time to set up	Recommended for further consideration for POA testing in NZ YES/NO
Rapid Antigen	45 mins	Estimated to be 40% for asymptomatic individuals, self- collecting samples with tests processed by testing centre staff	Swab or saliva	Self administered	None (self administered)	Currently no devices authorised for import or use in NZ to date.	Transfer to isolation (self or managed). Confirm result with laboratory based NAAT testing.	Confirm with RAPID PCR at POA. If confirmatory tests is +ve transfer to MIQ	Confirmation step would need laboratory input. IT requirements to record testing event and results. Quality of sample Low sensitivity in asymptomatic or early infectious period Scalability Regulatory framework around import and use of POCT for Covid-19 testing. Used overseas in high prevalence context such as in the UK where the test is performed frequently whereas NZ is a low prevalence context	Lack of oversight of sample collection, analysis and interpretation of results means this is an unreliable methodology Lower sensitivity testing modality will lead to false negatives and false positives means this is a high risk methodology	2-3 weeks for pilot or rollout	No
Rapid Antigen	75 mins	Average sensitivity [Cochrane review] 68.9% (95%CI: 61.8% to 75.1%) average sensitivity [ESR research of five RATs] 36.8% (95%CI: 30.3% to 43.9%)	Swab	Trained health care worker. 2 samples needed if all results to be confirmed by Lab based NAAT	Healthcare worker trained by accredited laboratory personnel	Currently no devices authorised for import or use in NZ to date.	Transfer to isolation (self or managed). Confirm result with laboratory based NAAT testing.	Confirm with RAPID PCR at POA. If confirmatory tests is +ve transfer to MIQ	5 kits evaluated by ESR and LabPlus Requires service provision by an accredited laboratory Sensitivity of method is improved when sample is taken by, and analysis is completed by a trained health worker. IT requirements to record testing even and results. Regulatory framework around import and use of POCT for Covid-19 testing.	Lower sensitivity testing modality, potentially leading to false negatives and false positives Places additional demands on healthcare testing workforce	3-4 weeks for pilot or rollout	Yes
RT-LAMP	75 mins	89% as demonstrated in New Zealand setting	Swab or saliva	Trained health care worker. 2 samples needed if all results to be confirmed by Lab based NAAT	Healthcare worker trained by accredited laboratory personnel	Low throughput analysers of this type are in very limited use in NZ settings e.g. ICU; for all samples run by LAMP, a laboratory based PCR is also completed.	Transfer to isolation (self or managed)	Transfer to MIQ	Requires same workforce and resource as RT-PCR but is less sensitive. Need to determine the availability of equipment with throughput sufficient to test up to 500 passengers in a timely way. Requires service provision by an accredited laboratory IT requirements to record testing event and results. Testing of saliva is regarded as effective when the test is done as part of a series.	Availability of equipment and lead in time to establish testing environment Lower sensitivity testing modality, compared to Rapid PCR	8-10 weeks for pilot or rollout (could potentially be 3-4 weeks for pilot if a low throughput device were found to be suitable)	No /
Rapid RT-PCR	120 mins	100% (comparator)	Swab or saliva	Trained health care worker. 1 sample only needed if sample type = swab.	Healthcare worker trained by accredited laboratory personnel	Low throughput analysers of this type are in extensive use in accredited medical laboratories around the country. No high throughput analysers currently being used in NZ.	Transfer to isolation (self or managed)	Transfer to MIQ	Already in use in New Zealand in other settings. Need to determine the availability of equipment with throughput sufficient to test up to 500 passengers in a timely way. Throughput estimated at 95 samples per hour. Will require multiple analysers at POA to efficiently process plane load of passengers. Space requirements for point of need testing - space will ned to meet laboratory specifications. Requires service provision by an accredited laboratory. IT requirements to record testing event and results. Testing of saliva is regarded as effective when the test is done as part of a series.	Availability of equipment and lead in time to establish testing environment	8-10 weeks for pilot or rollout (could potentially be 3-4 weeks for pilot if a low throughput device were found to be suitable)	Yes