Briefing

Advice on regulating laboratories for private COVID-19 testing

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To:	Hon Chris Hipkins, Minister for COVID-19 Response		
Copy to:	Hon Andrew Little, Minister of Health Hon Dr Ayesha Verrall, Associate Minister of Health (Public Health) Hon Peeni Henare, Associate Minister of Health (Maori Health) Hon Aupito William Sio, Associate Minister of Health (Pacific Peoples)		

Contact for telephone discussion

Name	Position	Telephone
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Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Advice on regulating laboratories for private COVID-19 testing

Security level:	IN CONFIDENCE	**Date:**	15 February 2021
To:	Hon Chris Hipkins, Minister for COVID-19 Response		

Purpose of report

1. We seek your agreement to introduce requirements for laboratories testing for COVID-19 to strengthen our ability to detect and respond to instances of COVID-19 in the community.

Summary

2. New, highly transmissible variants and high numbers of global cases heighten the need for preparedness and ongoing detection and surveillance of COVID-19 within the community. It is more important than ever that our policy settings support a robust and timely COVID-19 public health response.
3. Businesses and the public are eager for increased access to COVID-19 tests. The majority of tests for COVID-19 have been conducted by laboratories within the national laboratory network. These laboratories are all accredited to a high-quality testing standard and integrate into the public health response.
4. Laboratories external to this network ("external laboratories") have also expressed a desire to test New Zealanders for COVID-19.
5. Three main issues arise if external laboratories increase testing for COVID-19: no quality assurance for testing is in place; global shortages of laboratory consumables; and lack of integration into the public health response could risk an outbreak or spread of COVID-19.
6. Officials have considered a number of measures to mitigate these risks and recommend a combination of approaches is required to overcome the identified issues. These options (1-3) include: setting a minimum acceptable standard, retaining an ability to redirect and prioritise scarce resources if required, and integration into the wider public health response.
7. If you agree to progress these options (1-3), we recommend implementation through a section 11 Order under the COVID-19 Public Health Response Act 2020 (the Act). We envisage that a draft Order could be provided to you for signing in April/May 2021.
8. s 9(2)(h) [redacted]

Recommendations

We recommend you:

a) **Note:** that laboratories can currently test New Zealanders for COVID-19 without quality assurance risking false positives and a possible outbreak or spread of COVID-19, particularly with increasing numbers of infected people globally and the emergence of highly transmissible variants. Officials recommend requiring laboratories who test New Zealanders for COVID-19 to become IANZ-accredited to the international standard for testing people for COVID-19 (ISO15189) **Noted**

b) **Agree:** to require laboratories who test New Zealanders for COVID-19 to be IANZ-accredited to the international standard for testing people for COVID-19 (ISO15189) **(recommended)** **Yes/No**

c) **Note:** there is a global shortage of laboratory consumables and a limited supply of technically competent staff to process COVID-19 tests which, if further constrained, could impact on the ability of the public health response to prevent the outbreak or spread of COVID-19 **Noted**

d) **Agree:** to require laboratories that test New Zealanders for COVID-19 to prioritise or redirect resources to the national public health response if necessary and as directed by the Director-General of Health to prevent an outbreak or the spread of COVID-19 **(recommended)** **Yes/No**

e) **Note:** laboratories that test New Zealanders are not required to integrate into the national public health response by notifying all COVID-19 test results into the national testing repository to help prevent an outbreak or the spread of COVID-19 in New Zealand **Noted**

f) **Agree:** to require laboratories that test New Zealanders for COVID-19 to integrate into the national public health response, including by notifying all COVID-19 test results and inputting into the national testing repository **(recommended)** **Yes/No**

g) s 9(2)(h) [redacted] **Noted**

Dr Ashley Bloomfield
Director-General of Health
Date: 15/02/2021

Hon Chris Hipkins
Minister for COVID-19 Response
Date: 27/02/2021

It would be good to have a bit more information about how many labs are in this category and what consultation has taken place with them.

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Purpose of report

1. We seek your agreement to introduce requirements for laboratories testing for COVID-19 to strengthen our ability to detect and respond to instances of COVID-19 in the community.

Background

2. The global risk profile for COVID-19 has recently changed. Experts are of the view that COVID-19 may circulate in the community for years to come with other emerging variants. The COVID-19 Elimination Strategy has been updated to reflect the heightened risk from the virus and the need to prepare for it through surveillance to quickly detect cases in the community and stamp it out.
3. Our current Testing Strategy prioritises testing for at-risk and symptomatic people and does not recommend widespread asymptomatic testing of communities. This strategy aims to identify any community transmission in New Zealand and limit its spread through case identification and contact tracing.
4. All symptomatic testing should be carried out through the public health system. The Ministry's view is that there is limited to no benefit for routine asymptomatic testing by employers when COVID-19 prevalence in the community is nil to very low. The Ministry would only support asymptomatic testing undertaken through laboratories that are not part of the publicly funded system. Private testing results would also need to be distinguished from the national surveillance testing plan for reporting purposes.
5. In January 2020, you agreed to extend the prohibition on Point of Care (PoC) testing under the COVID-19 Public Health Response Act 2020 (Health Report 20210098) due to concerns over inaccurate and unreliable PoC testing kits that could hamper disease control efforts. This briefing builds on officials' initial advice last year on PCR laboratory testing for COVID-19 (Health Report 20201764).
6. This paper provides advice on options for regulating private laboratory-based testing for COVID-19. Pre-departure testing is not within the scope of this advice.

Quality assurance for COVID-19 testing in New Zealand

7. Nasopharyngeal RCT PCR testing is the "gold standard" for testing. The national laboratory network consists of a mix of public and private government-contracted laboratories. We rely on this network to provide high-quality nasopharyngeal RCT PCR testing. The network of laboratories manages available resources (human and consumables) and integrates results into a central national repository to support decisions around the public health response. The laboratories in this network are:
    a) **all accredited** to the International Accreditation New Zealand standards (IANZ) to ensure a minimum acceptable quality standard. IANZ assesses if a laboratory meets the technical and quality processes set out in the relevant international standard to test people for COVID-19 (ISO15189);

b) **integrated** into the public health response as test results are sent to the national testing repository and positives are notified to the medical officer of health for a timely response when an outbreak occurs (e.g. rapid contact tracing); and

c) **monitor resources** used to test for COVID-19 and are able to prioritise supply despite global shortages of certain key testing consumables (e.g. reagents and pipette tips).

8. IANZ has technical competence to verify medical laboratories to the relevant international standard for quality management system requirements for COVID-19 testing. These requirements include personnel (training and competency), equipment, data management, and end-to-end quality assurance. The accreditation can specify the test type, platform and scope to ensure appropriate use in the circumstances (e.g. RT PCR saliva testing for screening purposes).

9. New Zealanders[1] can also be tested for COVID-19 in external laboratories (private laboratories outside the network of laboratories). These laboratories could enhance access and assist the broader public health response. However, many of these external laboratories:

    a) do not currently hold IANZ accreditation to ensure quality of COVID-19 testing;

    b) do not integrate test results into the wider public health response risking a delayed response when positive cases present; and

    c) are not required to monitor and re-direct constrained resources to ensure their use in the most suitable circumstances for a timely and effective response, including on the highest risk people.

10. Only about one third of New Zealand's medical laboratories (19 laboratories) are accredited to the international standard to test people for COVID-19 (ISO15189). The remaining 42 laboratories are not accredited to the standard.

There is growing demand for routine asymptomatic COVID-19 testing by employers that sits outside our testing and surveillance strategy

11. Businesses are increasingly interested in testing employees for COVID-19 and may look to contract with laboratories that are not accredited or part of the publicly-funded network. s 9(2)(b)(ii), s 9(2)(ba)(i) [redacted]

12. s 9(2)(g)(i) [redacted] In January 2020, an external laboratory gained IANZ accreditation and will shortly begin COVID-19 testing for several businesses, including an aged care residence.

[1] **This briefing does not cover testing for goods, animals or the environment. MPI note export markets do not yet require assurance of employee testing for COVID-19.**

Routine private testing could undermine the health system's ability to effectively detect and respond to an outbreak or spread

13. Our policy settings need to support a robust and effective public health response. New, highly transmissible variants and high numbers of global cases heighten the need for preparedness and surveillance for COVID-19 for elimination efforts.

14. Business and public demand for COVID-19 testing is also likely to increase in the future. To quickly detect cases to avoid a COVID-19 outbreak, external laboratories need to meet testing quality standards with careful management of resources and integration into the public health response.

15. There are three main risks that could impact our ability to respond to a COVID-19 outbreak arising from private testing outside our current testing strategy:

    a) **inadequate testing quality means an outbreak or spread of COVID-19 could occur if an infected person acts on a false negative result and carries out their normal daily activities:** public health experts express concern over the testing for COVID-19 by external laboratories if testing does not meet an acceptable minimum standard. IANZ accreditation is currently not a requirement for COVID-19 testing outside the public health response and no enforcement mechanism exists if quality is not up to an acceptable standard. Rigorous clinical oversight is essential to maintain quality and to avoid false negatives or overlook weak positives;

    b) **inefficient use of scarce resources could mean we have inadequate staffing and consumables when most needed:** the lack of requirements on external laboratories to redirect consumables in short supply may mean vital resources (e.g. reagents, pipette tips, etc) are not being used where or when needed. Additionally, external laboratories are likely to call on the same trained professionals who would conduct testing for the public health response further limiting available resources in the event of an outbreak. New Zealand is currently carrying two months' supply of necessary stock. If an outbreak occurred and the demand increased on external laboratories, then this issue may pose a risk to New Zealand's public health response and ability to test at scale.

    c) **lack of integration into the public health response may compromise our ability to respond rapidly to positive cases (e.g. quickly begin contact tracing):** test results need to be integrated into the national public health databases and other systems with oversight and monitoring to ensure a co-ordinated public health response. If a positive case is unreported, overlooked or not acted upon because it has not been notified in the system then it would likely inhibit our ability to rapidly contact trace or put in place any other public health measures deemed necessary to limit the outbreak in the area (e.g. introducing face covering requirements on public transport).

Proposed options and analysis

16. The Ministry has assessed a range of potential measures to address the above risks. Three measures are recommended that should effectively mitigate the risks and concerns.

Table 1: Measures to mitigate the risks of permitting private COVID-19 testing

Option 1: require laboratories who test New Zealanders for COVID-19 to be accredited to IANZ and the relevant standard (ISO15189) **(recommended)** via Section 11 Order		
	Pros	**Cons**
Ensures quality	Sets minimum quality standard to reduce the risk of patients relying on a misleading test result and unintentionally spreading COVID-19 in the community.	• Cost to laboratories to become IANZ accredited.
Integration with the public health response		• Not integrated into wider public health response as no automated notification to national repository. However, this would be overcome if option 3 is also chosen. • Notification and identifying information would be required for contact tracing and public health response. • Require manual notification leading to delayed notification due to human error or oversight and impact our ability to respond quickly to an outbreak, unless IT systems are modified.
Ensures the most efficient use of scarce resources		• Impacts on surge capacity - public system would need to compete with private laboratories for scarce testing resources unless option 2 also chosen. • Not a good use of scarce resources if no clinical reason for test.
Other	• Normalises testing.	• s 9(2)(h) [redacted]

Option 2: Director-General of Health has the authority to direct laboratories to prioritise testing for the national public health response when necessary, such as during an outbreak via Section 11 Order **(recommended)**		
Ensures quality		• Testing quality not assured, unless minimum acceptable standard (option 1) also specified.
Integration with the public health response	Testing capacity available to support and inform decisions relating to the public health response when most needed.	• Not integrated into wider public health response as no automated notification to national repository. However, this would be overcome if option 3 is also chosen. • Notification and identifying information would be required for contact tracing and public health response. • Require manual notification leading to delayed notification due to human error or oversight and impact our ability to respond quickly to an outbreak, unless IT systems are modified.
Ensures the most efficient use of scarce resources	Increases overall testing capacity in the system which means we can more efficiently provide a picture of how widespread or contained a potential outbreak – allowing us to adjust our response accordingly. Ensures resources (consumables/staffing) are directed towards public health response in the event of an outbreak. The network of laboratories does not have to compete with external laboratories for the same testing resources.	• Routine testing by external laboratories during other times depletes scarce consumables (e.g. reagents) and may restrict overall surge capacity.
Other		• May override existing contractual obligations between employers and external laboratories.

Option 3: require laboratories to integrate into the public health response by notifying all COVID-19 test results to the medical officer of health for input into the national testing repository **(recommended)**		
Quality		• Testing quality not assured, unless minimum acceptable standard also specified (however, see option 1).
Integration	Integrates with wider public health system to allow for speedier contact tracing, etc. Allows monitoring for a notifiable disease with public health risk.	• Laboratories may face additional administrative burden if manual notification is required or financial costs associated with changes to IT systems. • If manual notification is preferred this could lead to delayed notification due to human error or oversight and impact our ability to respond quickly to an outbreak.
Resources		• Poor use of resources (consumables/staffing) in a low prevalence environment if no clinical reason to test.
Other	• Normalises testing. • Increases testing capacity.	• Change required to information collection practices for laboratories.

Option 4: prohibit external laboratories from testing New Zealanders for COVID-19		
Quality	Maintains quality standard (government only contracts with IANZ accredited laboratories for COVID-19 testing).	
Integration	Ensures integrated system for quicker contact tracing and case identification as all laboratories within the national laboratory network are required to notify public health units (PHUs) of any positive cases. Reduces confusion for the public on how private testing fits in with testing undertaken as part of the public health response.	
Resources	Retains surge capacity in the event of an outbreak, most efficient use of scarce resources/staffing.	• Lost opportunity to develop or train more personnel in New Zealand.
Other		• s 9(2)(h) [redacted] • Less access to testing for New Zealanders. • May discourage innovation. • May appear to discourage "Say Yes to the Test" message.

The Ministry recommends a combination of options 1, 2, and 3

17. The Ministry considers a combination of options is required to address the potential issues with external laboratories. A combination of options 1, 2 and 3 are recommended to ensure that a potential outbreak or spread of COVID-19 is prevented as they best address the issues identified by addressing:

    a) quality of testing through setting a minimum internationally recognised quality standard

    b) the integration of test results to activate and support a quick and effective public health response, and

    c) most efficient use of scarce resources to ensure they are available when required to address the public health risk posed by COVID-19.

18. s 9(2)(h) [redacted]

Equity

19. Under the 'Prepare for it' Pillar of the Elimination Strategy, access to testing must be easy and equity focused. Free of charge access to the PCR gold standard COVID-19 test is offered to all New Zealanders through the public health system if the testing criteria is met, including remote communities.

20. An objective of the COVID-19 Testing Strategy is to ensure access to testing is effective and equitable for all. If testing demands increased on external laboratories by those who could easily afford such a test, then it may cause inequitable outcomes for those who could not afford such a test.

21. While many employers may consider employer-funded COVID-19 testing for employees as a benefit to those employees, there is a risk that some vulnerable and low-risk employees may feel compelled to take a test despite no public health rationale, no clinical indication and no legal obligation.

Te Tiriti o Waitangi consideration

22. If New Zealanders can access a private laboratory to be tested then it could be seen to support the principle of Tino Rangatiratanga – Māori self-determination – by providing Māori with autonomy to initiate tests themselves or for their communities through another channel, as deemed appropriate.

23. However, experts consider that any private testing needs to be of a specified minimum acceptable standard for New Zealanders (including Māori) to be relied on, and to ensure the public health response to COVID-19 can be delivered. It is considered all New Zealanders need access to high quality healthcare.

Next steps

24. If you agree to progress options 1-3, we recommend progressing these through a section 11 Order under the COVID-19 Public Health Response Act 2020 (the Act). We would envisage that a draft Order could be provided to you for signing in April/May 2021.

ENDS.