Briefing

Further measures to manage COVID-19 testing capacity and delivery (COVID-19 Public Health Response Amendment Bill)

Date due to MO:	N/A	**Action required by:**	Friday 9 July 2021
Security level:	IN CONFIDENCE	**Health Report number:**	20211433
To:	Hon Chris Hipkins, Minister for COVID-19 Response		

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☐ See Minister's Notes ☐ Withdrawn

Comment:

Further measures to manage COVID-19 testing capacity and delivery (COVID-19 Public Health Response Amendment Bill)

Security level:	IN CONFIDENCE	**Date:**	Friday 2 July 2021
To:	Hon Christ Hipkins, Minister for COVID-19 Response		

Purpose of report

1. This briefing provides you with analysis and options for approval to complete drafting instructions on laboratory testing requirements for inclusion in the COVID-19 Public Health Response Act Amendment Bill (the Bill).

Summary

2. The private market for providing COVID-19 tests has the potential to increase, particularly in light of requirements for pre-departure testing for New Zealanders intending to travel overseas. Officials consider that three main issues arise if laboratories not contracted to deliver testing for the public health response increase their testing for COVID-19:
    a. no quality assurance for testing is in place, which may lead to concerning levels of false negatives or positives
    b. global shortages of laboratory consumables may be exacerbated by consumables being used for non-public health response testing, and
    c. the lack of integration into the public health response could risk an outbreak or spread of COVID-19.
3. You have previously received advice that some of these issues may be addressed through a COVID-19 Public Health Order (and Order). This is progressing.
4. However, some measures to address these issues require a change to the COVID-19 Public Health Response Act. There is an opportunity to do this through the Bill. Those changes are:
    a. to require non-public health contracted laboratories that test New Zealanders for COVID-19 to prioritise or redirect resources to the national public health response
    b. to requisition consumables (such as reagent and swabs) required for COVID-19 testing from laboratories for the national public health response.

5. Cabinet has agreed the high-level policy for these measures, and empowered you to make additional policy decisions for drafting purposes consistent with the policy intentions agreed by Cabinet.

6. The additional policy approvals required to provide in the Bill drafting for these laboratory testing capacity and delivery measures are:

    a. to include in the Bill a provision that empowers the Minister for COVID-19 Response to approve an Order for the purposes of:

        i. testing consumables held by laboratories to be requisitioned for the use and reallocation for the national public health response (with an appropriate compensation mechanism should that be exercised), and

        ii. requiring any laboratories (either contracted to the public health response or not) if they are undertaking COVID-19 testing, to do so for the public health response only (with an appropriate remuneration provision should that be exercised).

Recommendations

We recommend you:

a)	**Note** that Cabinet agreed to include in the COVID-19 Public Health Response Amendment Bill (the Bill) provisions to: i. regulate quality control and minimum standards ii. require reporting of COVID-19 test results into the public health national testing repository, and iii. manage the supply of testing consumables.	**Noted**
b)	**Note** that Cabinet authorised you, in your capacity as Minister for COVID-19 Response, to make any necessary further policy decisions that may arise during the Bill drafting process, consistent with the policy intentions agreed by Cabinet.	**Noted**
c)	**Note** that a COVID-19 Public Health Order under section 11 is currently being progressed to require all laboratories who test New Zealanders for COVID-19 to be IANZ-accredited and to integrate into the national public health response, including by notifying all COVID-19 test results and inputting into the national testing repository.	**Noted**
d)	**Agree** to include in the Bill a provision that empowers the Minister for COVID-19 Response to approve an Order for the purposes of: i. testing consumables held by laboratories to be requisitioned for the use and reallocation for the national public health response, and ii. requiring any laboratories (either contracted to the public health response or not) if they are undertaking COVID-19 testing, to do so for the public health response only.	**Yes/No**
e)	**Agree** to include in the Bill a provision to provide a compensation mechanism for laboratories whose consumables have been requisitioned (aligned with	**Yes/No**

current compensation provisions for requisitioning of materials found in the Health Act 1956 and other similar legislation).

f) **Agree** to include in the Bill a provision to provide that a laboratory not currently providing testing services for the public health response change to do so as a result of such an Order, shall be paid for those services at an appropriate market rate. **Yes/No**

g) **Agree** to include in the Bill a provision to provide for disputes regarding compensation to be decided by the District Court, with no right of appeal (aligned with the provisions for compensation under section 87(6) of the Health Act 1956). **Yes/No**

h) **Direct** officials to issue drafting instructions to Parliamentary Counsel Office to give effect to these decisions in the drafting of the Bill. **Yes/No**

PP.

Maree Roberts
Deputy Director-General, System Strategy and Policy
Date: 1/07/2021

Hon Chris Hipkins
Minister for COVID-19 Response
Date: 10/7/2021

Further measures to manage COVID-19 testing capacity and delivery (COVID-19 Public Health Response Amendment Bill)

Background

1. The private market for providing COVID-19 tests has the potential to increase, particularly in light of requirements for pre-departure testing for New Zealanders intending to travel overseas. Officials consider that three main issues arise if laboratories not contracted to deliver testing for the public health response increase their testing for COVID-19:

    a. no quality assurance for testing is in place, which may lead to concerning levels of false negatives or positives

    b. global shortages of laboratory consumables may be exacerbated by consumables being used for non-public health response testing, and

    c. the lack of integration into the public health response could risk an outbreak or spread of COVID-19.

2. To address these risks, you have previously received advice regarding the regulation of laboratories for private COVID-19 testing[1] [HR 20210113 refers]. That advice sought agreement to require laboratories who test New Zealanders for COVID-19 to:

    a. be IANZ-accredited to the international standard for testing people for COVID-19 (ISO15189)

    b. 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, and

    c. integrate into the national public health response, including by notifying all COVID-19 test results and inputting into the national testing repository.

3. While progressing the policy work for regulating laboratory testing, legal advice was received clarifying that some desired measures would not be able to be put in place through a COVID-19 Public Health Order (Order) and would require an amendment to the primary legislation instead.

4. Providing for different levels of regulation for laboratories which are currently contracted to deliver COVID-19 testing under the public health response and laboratories which are not contracted for the public health response, would not be permissible under Orders currently. For example: it would only be permissible to enable non-public health contracted laboratories to undertake private testing if network laboratories were similarly enabled; and any ability to requisition private stock of consumables would also need to be provided for in primary legislation.

[1] COVID-19 testing in this context includes testing humans for both infection with and immunity to the COVID-19 virus.

5. The laboratory testing work stream was subsequently split into two different pathways – changes that could be achieved through an Order, and changes that needed to be included in the COVID-19 Public Health Response Act 2020 (the Act) via the upcoming COVID-19 Public Health Amendment Bill (the Bill). The following table confirms which mechanisms will be used to achieve which outcomes:

Mechanism	Outcome
Section 11 COVID-19 Public Health Order	• Require all laboratories who test New Zealanders for COVID-19 to be IANZ-accredited. • Require all laboratories to integrate into the national public health response, including by notifying all COVID-19 test results and inputting into the national testing repository. • Require all laboratories to report regularly to the Ministry of Health on the number of COVID-19 testing consumables they hold in stock[2].
COVID-19 Public Health Amendment Bill	• Require non-public health contracted laboratories that test New Zealanders for COVID-19 to prioritise or redirect resources to the national public health response. • Requisition consumables (such as reagent and swabs) required for COVID-19 testing from laboratories for the national public health response.

6. To enable the inclusion of laboratory testing requirements in the Bill, Cabinet has agreed [SWC-21-MIN-0067 and CAB-21-MIN-0167 refer] to include in the Bill provisions to:
   a. regulate quality control and minimum standards
   b. require reporting of COVID-19 test results into the public health national testing repository, and
   c. manage the supply of testing consumables.
7. Cabinet also authorised you, in your capacity as Minister for COVID-19 Response, to make any necessary further policy decisions that may arise during the Bill drafting process, consistent with the policy intentions agreed by Cabinet.

Proposed approach to laboratory testing requirements in the Bill

8. While these measures are not required currently, nor are they foreseen to be required in the immediate future, it is prudent to provide for this in primary legislation should New Zealand experience a significant resurgence in COVID-19 in the future. Additionally, as the Act is intended to provide a "blueprint" for future pandemic response legislation, there is

[2] This provision has not been included in the currently being drafted Order for regulating laboratory testing as it is not currently needed. If and when required, an amendment to the Order will be drafted to include this provision.

value in ensuring this issue is addressed in the Act, should it be repurposed in the future for another pandemic response.

9. A tiered approach is recommended to managing laboratory testing regulation, responsive to the public health needs at the time (scenarios) and empowered by the appropriate mechanisms (contracts, Orders and primary legislation). This approach will progress through the various levers available to the Ministry of Health to manage the relationship with all laboratories and requirements placed on them, including the laboratories not currently contracted to the public health system.

10. The tiered approached is summarised as follows:

Scenario One (Current state, no community cases of COVID-19) • NZ has sufficient consumables and testing capacity to meet testing needs through the use of laboratories currently contracted to deliver testing for the public health response. • An increase in demand for COVID-19 tests provided outside of the public health response has raised concerns regarding the accuracy of some COVID-19 testing, particularly if the risk of false negatives increases. • That increase in demand has also raised concerns that laboratories not contracted as part of the public health response are not required to report the results of tests to the Ministry of Health – which may undermine surveillance and testing programmes for the public health response.	
Existing levers: • Contractual relationships with laboratories currently contracted to deliver testing for the public health response (either through MoH or DHBs) could require labs to meet ISO15189. But there is no legislative requirement for laboratories to meet any particular standard beyond being registered and competent under the Health Practitioners Competency Act 2003.	**Additional levers:** • a section 11 Order under the COVID-19 Public Health Response Act could be used to require any laboratory in NZ undertaking COVID-19 testing be accredited to the appropriate ISO15189 standard; and • report all positive cases immediately and all other testing outcomes into the national testing repository as soon as possible. This Order is currently being drafted and progressed. *No legislative change is required for this scenario.*

Scenario Two (moderate NZ resurgence) • Due to an increase in global demand for supplies, or an increased domestic demand due to a resurgence, there is concern that NZ may not have sufficient consumables and testing capacity to meet increased needs. • A better picture is needed of what resources NZ has available that may be deployed for the public health response to enable informed decision making.	
Existing levers: Contractual relationships as above, plus: • the Minister of Health can issue a direction to DHBs under the Crown Entities Act 2004 and New Zealand Public Health and Disability Act 2000 to give effect to government policy. This was previously used in 2020 to direct DHBs to nationalise consumables for the COVID-19 response against global shortages of masks, gloves and other consumables.	**Additional levers:** S11 Order as above, plus: • the section 11 Order could be amended to require all laboratories to report to the Ministry of Health the number of consumables they hold in stock at any time. *Section 11 Order could be amended through current processes (though is not being provided for currently as it is not required), no change needed to the Act.*

Scenario Three (significant NZ resurgence)	
• As a result of a significant resurgence of COVID-19 in New Zealand, and insufficient capacity through laboratories currently contracted to deliverer testing to the public health response, it is desirable to ensure that any COVID-19 testing taking place, and consumables to facilitate that testing, is prioritised for the public health response.	
Existing levers: Contractual relationship and DHB Direction as above, plus: • MoH and DHBs can negotiate private contracts with laboratories not currently contracted to deliver testing for the public health response.	**Additional levers:** S11 Order as above, plus: • the COVID-19 Public Health Response Act cold be amended to provide the ability for the Minister, through a section 11 Order, to provide for: o testing consumables held by laboratories to be requisitioned for use and reallocation for the national public health response (compensation will also ned to be provided for in the primary legislation); and o requiring any laboratories (either contracted to the public health response or not) if they are undertaking COVID-19 testing, to do so for the public health response only (with appropriate compensation). *Amendment to the COVID-19 Public Health Response Act through the amendment Bill is required to provide for this.*

Scenario Four (State of Emergency in NZ)
• A resurgence of COVID-19 in New Zealand is severe and widespread enough to warrant the declaration of a State of Emergency. Laboratory testing capacity is overwhelmed.
Existing levers: Contractual relationship, DHB Direction and use of s11 Orders as above, plus: • existing emergency powers (such as those found in section 90 of the Civil Defence and Emergency Management Act 2002) can be used to requisition property including medical supplies, or equipment, materials or supplies by placing them under the control and direction of a Controller or a constable, or person authorised by that Controller or constable.

11. Under scenarios two and three, Orders can be used to managed COVID-19 testing capacity and delivery. You have provided policy approvals for the drafting of this Order, and it is progressing currently.

12. Under scenario three, if New Zealand experiences a significant resurgence where testing and consumables need to be prioritised to support the public health response, the legal mechanism to respond to this must be provided for in primary legislation through an amendment to the Act.

13. In order to provide the legal mechanism for this approach, should it ever be needed, it is recommended that you agree to include in the Bill the following provisions:

    a. empower the Minister for COVID-19 Response to approve an Order for the purposes of:

        i. requisitioning testing consumables held by laboratories for the use and reallocation for the national public health response, and

        ii. requiring any laboratories (either contracted to the public health response or not) if they are undertaking COVID-19 testing, to do so for the public health response only (with appropriate compensation)

    b. provide a compensation mechanism for laboratories whose consumables have been requisitioned (aligned with current compensation provisions for requisitioning of materials found in the Health Act 1956 and other similar legislation)

c. provide that should a laboratory not currently providing testing services for the public health response change to do so as a result of such an Order, shall be paid for those services at an appropriate market rate, and

d. provide for disputes regarding compensation to be decided by the District Court, with no right of appeal (aligned with the provisions for compensation under section 87(6) of the Health Act 1956).

Equity

14. Should the mechanisms included in the Bill be applied, laboratories not currently contracted to deliver testing for the public health response will be affected, particularly if consumables are requisitioned or they feel inadequately remunerated for testing as part of the public health response. However, a compensation and remuneration mechanism in the Act aligned with those currently in the Health Act 1956 and other primary legislation will ensure that laboratories are appropriately compensated for this.

Next steps

15. Pending your approval, officials will issue drafting instructions to Parliamentary Counsel Office to draft these provisions into the Bill.

16. Officials are engaging in targeted stakeholder engagement about the Bill in July (prior to Select Committee) in order to test provisions of the Bill with those who will be implementing them. Public Health Unit representatives and Medical Officers of Health are trusted critical friends for matters such as this and will be confidentially asked for their feedback on these provisions of the Bill.

17. Minister Verrall has expressed an interest in this aspect of the Bill. It is recommended that you forward this briefing to her.

ENDS.