Briefing

COVID-19 Public Health Response (Point of Care Tests) Order 2021: Final Order for Signature

Date due to MO:	9 April 2021	**Action required by:**	14 April 2021
Security level:	IN CONFIDENCE	**Health Report number:**	20210772
To:	Hon Chris Hipkins, Minister for COVID-19 Response		

Contact for telephone discussion

Name	Position	Telephone
Dr Ashley Bloomfield	Director-General of Health	s 9(2)(a) [redacted]
Maree Roberts	Deputy Director-General, System Strategy and Policy	

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

COVID-19 Public Health Response (Point-of-Care Tests) Order 2021: Final Order for Signature

Security level:	IN CONFIDENCE	**Date:**	9 April 2021
To:	Hon Chris Hipkins, Minister for COVID-19 Response		

Purpose of report

1. This report recommends that you sign the attached COVID-19 Public Health Response (Point-of-Care Tests) Order 2021 (the Order). The Order prohibits the importation, manufacture, supply, sale, packing and use of COVID-19 point-of-care (POC) tests, except where exempt or authorised by the Director-General of Health (the Director).

Summary

2. New Zealand relies on highly sensitive Reverse Transcription Polymerase Chain Reaction (PCR) tests to prevent and limit the risk of outbreak or spread of COVID-19. PCR tests are considered the 'gold standard' because they are highly accurate, reliable and provide fairly rapid results (within 24-48 hours). The use of less sensitive tests could undermine the current testing approach.

3. A POC test is any kit or other material that is intended to:

   a. test for SARS-CoV-2 or COVID-19 infection[1] or immunity (whether current or historical) in an individual; and

   b. produce a result without analysis at a laboratory.

4. On 22 April 2020, Medsafe issued a notice prohibiting the importation, manufacture, sale, supply and use of POC tests, unless authorised or exempt by the Director-General, due to concerns over the accuracy and reliability of those tests. The Notice will expire on 21 April 2021 and cannot be renewed.

5. On 6 February 2021 you agreed to formally regulate the prohibition on importing, manufacturing, supply, sale or use of all POC tests, unless exempted or authorised by the Director-General, through a section 11 Order under the COVID-19 Public Health Response Act 2020 [HR20210652 refers]. You also agreed to include a prohibition on persons 'packing' POC tests [HR 20210652 refers].

[1] **Making the distinction between the virus and the disease.**

6. On 30 March 2021 Ministerial consultation was completed with no amendments required.

7. The attached draft Order seeks to prevent the spread or outbreak of COVID-19 by ensuring that testing for COVID-19 in New Zealand provides trustworthy results and any new test types are supported by science.

8. Specifically, the Order prohibits a person from importing, manufacturing, supplying, selling, packing, or using a POC test unless the Director-General has:

   a. authorised the person's activity; or

   b. exempted the point-of-care test from the prohibition.

9. Officials have worked closely with the New Zealand Customs Service, the Ministry for Primary Industries, the Ministry of Business Innovation and Employment, and other stakeholders to develop the proposed Order and will continue to work together to ensure the Order is implemented promptly.

10. Once signed, the Order will be gazetted on 15 April 2021 and come into force on 17 April 2021.

Recommendations

We recommend you:

a)	**Note** that a Notice under the Medicines Act 1981 is in force until 21 April 2021 to prohibit the importation, manufacture, supply, sale or use of point-of-care COVID-19 tests (unless exempt) and that this Notice cannot be renewed.	**Noted**
b)	**Note** that officials advise the COVID-19 Public Health Response (Point-of-Care Tests) Order 2021 is in line with the purposes of the COVID-19 Public Health Response Act 2020, to prevent, and limit the risk of, the outbreak or spread of COVID-19.	**Noted**
c)	**Note** that following Ministerial consultation, the COVID-19 Public Health Response (Point-of-Care Tests) Order 2021 has been finalised for your approval.	**Noted**
d)	**Note** that the COVID-19 Public Health Response (Point-of-Care Tests) Order 2021 gives effect to the policy previously agreed in HR20210098, by prohibiting the importation, manufacture, supply, packing, sale and use of point-of-care tests, unless exempted or authorised.	**Noted**
e)	**Agree** to sign the attached COVID-19 Public Health Response (Point-of-Care Tests) Order 2021.	**Yes/No**

Dr Ashley Bloomfield

Director-General of Health

Date: 8/04/2021

Hon Chris Hipkins

Minister for COVID-19 Response

Date: 9/4/2021

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Background

1. To prevent and limit the spread of COVID-19, New Zealand has implemented a robust testing plan that involves the use of highly sensitive tests to detect the virus. Nucleic Acid Amplification Tests, such as Reverse Transcription Polymerase Chain Reaction (PCR) tests, are the 'gold standard' because they are highly accurate, reliable and provide fairly rapid results (within 24-48 hours). The use of less sensitive tests, such as point-of-care (POC) tests could undermine the current testing approach.

2. Point-of-care (POC) tests are any kit or other material that is intended to:

    a. be used to test for SARS-CoV-2 or COVID-19 infection or immunity (whether current or historical) in an individual; and

    b. produce a result without analysis at a laboratory.

3. Unauthorised POC tests carry the following risks:

    a. concerns from scientific experts over the accuracy of POC tests and their potential to provide patients with a misleading result regarding their COVID-19 infection or immunity status;

    b. potential misuse and misinterpretation by the patient or public leading to risky behaviours and the risk of an outbreak or spread of COVID-19;

    c. POC tests being used instead of quality-assured and highly accurate PCR tests, thereby undermining the effectiveness of the PCR testing system; and

    d. a lack of integration into the test results repository and wider contact tracing process, which could make detection and management of positive cases difficult in the public health system.

4. Medsafe issued a Notice on 22 April 2020 under section 37 of the Medicines Act 1981 (the Notice) prohibiting POC tests, due to concerns over the accuracy and reliability of these tests. The Notice restricts the importation, manufacture, sale, supply and use of POC tests, unless or exempt or authorised by Medsafe. The Notice expires on 21 April 2021 and cannot be renewed under the Medicines Act 1981.

5. You agreed to continue the prohibition of the importation, manufacture, supply, sale or use of POC tests through an Order issued under section 11 of the COVID-19 Public Health Response Act 2020 (the Act). You also agreed on prohibiting 'packing' (enclosing in a container for the purpose of sale or supply) of POC tests. This would be consistent and related to other prohibited testing activities [HR20210652 refers].

6. On 30 March 2021 Ministerial consultation was completed with no amendments required.

Contents of the Point of Care Test Order

General Prohibition of POC tests

7. The proposed Order defines a POC test and provides for a general prohibition of POC tests including the importation, manufacture, supply, sale, packing or use of POC tests unless pursuant to an exemption or authorisation by the Director-General.

Ability to authorise certain persons

8. The Order provides the Director-General with the power to authorise certain persons (including organisations) to import, manufacture, supply, sell, pack, or use POC tests if satisfied it would be consistent with the purpose of the Act and not cause any significant risk to the public health response.

9. This power is intended to enable the Director-General to allow suitable organisations (e.g. Environmental Science and Research) who are subject to sufficient controls and safeguards to use certain POC tests for legitimate use and purposes (e.g. scientific research).

Ability to exempt certain tests

10. The Director-General will have the power to exempt certain POC tests from some or all prohibitions under the notice to accommodate for future technological or scientific advancements. We anticipate this exemption power will be used when the Director-General considers that a POC test has advanced to the point where it no longer poses quality or reliability concerns and should be allowed to be imported, manufactured, supplied, packed, sold or used in New Zealand.

Director-General can set conditions

11. The Order provides the Director-General with the ability to set conditions when authorising persons or exempting POC tests to prevent the outbreak and spread of COVID-19, or where necessary to facilitate an appropriately coordinated public health response. These powers are consistent with those under section 12(1)(d) of the Act.

12. The Director-General's power to set conditions enables him or her to apply a broad range of controls, including specifying who can perform the test, who can be tested, where testing can be performed, and for what purpose.

13. The ability to set conditions is necessary because some tests may be appropriate for certain applications and when provided within certain contexts, such as when performed with oversight from an appropriately qualified health practitioner. However, the same test might not be appropriate for use by the general public.

Pre-requisites for making a section 11 Order

14. Under the COVID-19 Act, an Order may be made if either:

    a. a state of emergency has been declared (under the Civil Defence Emergency Management Act 2002);

    b. an Epidemic Notice is in force (under the Epidemic Preparedness Act 2006); or

    c. it has been authorised by the Prime Minister.

15. There is currently an Epidemic Notice in place, which allows Orders to be made under section 11 of the COVID-19 Act.

16. As the Minister for COVID-19 Response, you may make Orders under section 11 of the COVID-19 Act.

17. To make an Order under section 11 you must:

    a. have received advice from the Director-General about:

        i. the risks of the outbreak or spread of COVID-19; and

        ii. the nature and extent of measures that are appropriate to address those risks; and

    b. be satisfied that the proposed Order does not limit or is a justified limit on the rights and freedoms in the New Zealand Bill of Rights Act 1990 (NZBORA);

    c. consult with the Prime Minister, Ministers of Health and Justice, and any other Ministers you think necessary; and

    d. be satisfied that the Order is appropriate to achieve the purposes of the Act.

18. I understand that you have consulted with the Prime Minister and Ministers of Health and Justice, and other relevant Ministers on the draft Order.

19. My advice about the risks of the outbreak or spread of COVID-19 and the nature and extent of measures that are appropriate to address those risks is set out in this report.

Public health rationale for the Order

20. New Zealand's Elimination Strategy means that every case of COVID-19 must be identified accurately and early, in order to prevent wider outbreak or spread. This means we need to use the most sensitive testing methods available. The use of less sensitive tests may give rise to the risk of the outbreak or spread of COVID-19. A prohibition on the use or supply of unreliable POC tests by the general public would reduce this risk.

21. You have previously been provided with a detailed public health rationale for the proposed Order [HR20210098 refers].

New Zealand Bill of Rights Act 1990

- s 9(2)(h) [redacted]
- [redacted]
- [redacted]

Equity

25. An objective of the COVID-19 Testing Strategy is to ensure that access to testing is effective and equitable for all groups, in particular, Māori.

26. The 'gold standard', PCR testing, is free to anyone who meets the criteria for testing, irrespective of age or region.

Te Tiriti o Waitangi considerations

27. POC tests could be seen to support the principle of Tino Rangitiratanga – Māori self-determination – by providing Māori with autonomy to test themselves or their communities as they deem appropriate.

28. However, POC tests are not yet an acceptable standard deemed by the regulator, MedSafe, so reliance on a POC test would not be consistent with the principle of active protection. It is considered all New Zealanders need access to high quality healthcare. If the position on POC tests changes, then the Ministry will consult with Iwi/Māori groups.

Implementation

29. Officials have worked closely with the New Zealand Customs Service, the Ministry for Primary Industries, the Ministry of Business Innovation and Employment, and other stakeholders to develop the proposed Order, and will continue to work to ensure the Order is implemented promptly.

Next steps

30. To ensure that there are no regulatory gaps once the Notice expires on 21 April 2021, and if you are satisfied that the grounds for making the Order are met, and that it is appropriate to achieve the purpose of the Act, we recommend you sign the attached Order on, or by, 14 April 2021.

31. If you sign the Order on, or by, 14 April 2021, it will be gazetted on 15 April 2021, and come into force on 17 April 2021.

ENDS.