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22 March 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H202200700

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 28 January 2022. You specifically asked:

> *"Can we please see the 20 October order (or whatever was the mechanism) by which the Ministry authorised the RATs trial among MBIE and the 29 businesses? Presumably the authorisation is in writing in one or more documents.*
> *We would like copy(ies) please with urgency under the OIA because of the public interest in the government's management of the pandemic in general, the current interest in the role of RATs specifically in managing the pandemic, and the significance of the RATs trial being conducted with devices and methods that previously had not been allowed in order to protect public health."*

I have identified three memoranda within scope of your request. All documents are itemised in Appendix 1 and copies of the documents are enclosed and released to you in full.

Please note regarding the availability of rapid antigen tests (RATs) in phase 2 of New Zealand's Omicron response, there is an increased use of RATS alongside PCR tests. The Ministry will use its supply of RATs to support those that need them the most – critical workers in the health and disability sector and our priority populations.

Other critical businesses and organisations can keep their critical workers working if they become a close contact of someone with COVID-19 by accessing RATS through the Close Contact Exemption Scheme.

Further information on RAT supplies is available in a press statement here: www.beehive.govt.nz/release/government-secures-extra-36-million-rapid-antigen-tests.

I trust this information fulfils your request. Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases

Nāku noa, nā

Jo Pugh
Acting Group Manager
COVID-19 Testing and Supply

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	13 October 2021	Memo: Seeking an authorisation for organisations under the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 with Appendix	Released in full.
2	18 October 2021	Memo: Seeking an authorisation for one organisation under the COVID-19 Public Health Response (Point-of-care Tests) Order 2021	
3	10 November 2021	Memo: Gazetting Notice: Point-of-Care Test Authorisations with Appendix	

MINISTRY OF HEALTH
MANATŪ HAUORA

Memo

Seeking an authorisation for organisations under the COVID-19 Public Health Response (Point-of-care Tests) Order 2021

Date:	13 October 2021
To:	Dr Ashley Bloomfield, Director-General of Health
From:	Darryl Carpenter, Group Manager – Testing and Supply
For your:	Action

Purpose of report

1. The purpose of this report is to seek authorisations under the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 (the order) for organisations importing, supplying and/or using point-of-care rapid antigen tests (RATs) for SARS-CoV-2 or COVID-19.

Background and context

2. The COVID-19 Public Health Response (Point-of-care Tests) Order 2021 came into force on 22 April 2021, replacing the Notice Under Section 37 of the Medicines Act 1981 (Gazette 2020-go1737)
3. This Order prohibits a person from importing, manufacturing, supplying, selling, packing, or using a point-of-care test for SARS-CoV-2 or COVID-19 unless the Director-General of Health has:
    a. authorised the person's activity; or
    b. exempted the point-of-care test from the prohibition.
4. The intent of the Order is to prevent testing for COVID-19 using unverified or unaccredited methods or tools and prevent the misinterpretation of any results.

Authorisation is sought for business organisations wishing to import, supply and /or use point of care rapid antigen tests

5. This Order had the known effect of effectively prohibiting point of care testing devices and consumables for COVID-19 testing. This memo seeks authorisation consistent with section 8 of the Order for businesses signed up to the Business Charter owned by the Ministry of Business, Innovation, and Employment (MBIE) (Appendix 1) seeking to import and supply and/or use point-of-care rapid antigen tests.
6. Without authorisation, the relevant testing devices and consumables imported by the business organisations will be seized by Customs upon arrival in New Zealand or the business

organisations will not be able to use any tests that have been successfully authorised for import and supply.

7. The business organisations for whom authorisation is being sought are those signed up to the MBIE Business Charter as follows:

List of businesses:

Mainfreight,

Foodstuffs North Island,

Genesis,

Hynds Pipe Systems,

Mercury,

Summerset Group,

Wellington Airport,

Christchurch Airport,

Sky NZ,

Queenstown Airport,

Spark,

Vodafone,

The Warehouse Group,

ANZ Bank,

Contact Energy,

Fulton Hogan,

Woolworths NZ,

Fletcher Building,

Chorus, Carter

Holt Harvey,

Meridian Energy,

DHL Express NZ,

Air NZ,

Auckland Airport,

Silver Fern Farms, and

Turners and Growers.

8. The Business Charter defines the scope, purpose, and requirements of the initial phase of use of RATs by business organisations.

9. Examples of proposed Standard Operating Procedures (SOP) and Instructions for interpretation of results are provided for your information in Appendix 2 and Appendix 3 respectively.

10. The Ministry of Health will provide guidance on operational protocols and requirements for reporting on use of RATS and reporting of results, including follow up and mandatory reporting of positive results.

11. Regular meetings and reporting mechanisms will be established between MBIE and the Ministry to monitor and learn from the initial phase of RAT use by businesses.

12. The point-of-care RATs the businesses are currently seeking authorisation to import, supply and/or use are detailed as follows:

Point-of-care rapid antigen test
SARS-CoV-2 Rapid Antigen Test (SD Biosensor) (Nasal)
PanBio COVID-19 Ag Rapid (Nasal)
CareStart COVID-19 Antigen (Nasal)

13. The number of brands of RAT on this list may be increased over time, and authorisation of additional brands will be the subject of subsequent memos.

14. On 20 August 2021 you authorised the following suppliers to import and supply the named tests for the Ministry of Health Testing and Supply Group:

Supplier Name	**Point-of-care rapid antigen test**
Roche Diagnostics NZ Ltd	SARS-CoV-2 Rapid Antigen Test (SD Biosensor) (Nasal)
Abbott Rapid Diagnostics	PanBio COVID-19 Ag Rapid (Nasal)
Pantonic Health	CareStart COVID-19 Antigen (Nasal)

15. On 16 September 2021 you authorised the named suppliers (in the table above) to import and supply the named tests for organisations *other than* the Ministry of Health Testing and Supply Group. Your authorisation was approved pending advice (or confirmation of advice) from the COVID-19 Testing Technical Advisory Group (CT-TAG) that these tests are sufficiently sensitive and specific. This advice, or confirmation of advice has yet to be received but is on the agenda for CT-TAG on 14 October 2021.

Recommendations

It is recommended that you:

1.	Note	The known effect the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 had of effectively prohibiting point-of-care testing devices and consumables	Yes/No
2.	Approve	The authorisation of the businesses listed in paragraph 7 of this report, as signed up to the MBIE Business Charter under the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 to allow the import, supply and/or use of the named point-of-care antigen devices.	Yes/No
2.	Approve	The authorisation of the named suppliers under the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 to allow the import and supply of the named point-of-care antigen devices to the authorised businesses, pending the advice sought from the COVID-19 Testing Technical Advisory Group (CT-TAG).	Yes/No

Thanks - yes, and I would like to see the advice once developed and also please ensure CT-TAG is involved in the process to review & sign-off on the operational protocols being developed.

Signature _____ Date: 13/10/21

Dr Ashley Bloomfield

Director-General of Health

Appendix 1

Business Charter

Scope and purpose of the initial phase

Businesses across New Zealand are looking for ways to meet their health and safety obligations within the COVID-19 response. In order to enable businesses to take all reasonable steps as part of their health and safety activities and assessment, the Ministry of Health (MOH) has approved a cohort of businesses to use rapid antigen tests in their worksites for asymptomatic testing.

Employees, contractors and site visitors may be given rapid tests to take as a condition of entry to worksites, or as requested by their employer. Each of the businesses involved in the trial will create operational processes which set out when employees, contractors and site visitors may need to take a rapid antigen test.

Principles

1. The trial is **led and funded by business**, enabled by government and public health-aligned.
    - Government is not mandating the use of rapid antigen tests for businesses. Businesses should get their own independent legal advice where they are considering making the use of rapid antigen tests mandatory or a condition of employment.
    - MBIE will support business in creating operational processes.
    - The trial will operate within legislative and regulatory parameters.
    - Test kits must be approved and can only be used for the purposes of the trial at this stage.
2. **Move fast and start small**, so issues can be identified and improvements made quickly.
3. Intent is to give businesses greater **confidence to operate and meet their health and safety obligations**.
4. We will **share lessons openly** and resolve any issues through an agreed governance and reporting structure.
5. Rapid antigen testing **doesn't replace or interfere with any existing public health requirements**.

    Business-run testing must have appropriate pathways to the health system (for example, management of indeterminate, invalid or positive results).
6. This trial is taking place **within the existing public health situation and strategy** – we acknowledge that the use of rapid antigen testing may shift as context changes.

By signing up to this trial, you agree to:

- Work with MBIE and the MOH on creating operational protocols which set out:

  - requirements to store, administer, and read the tests in accordance with the manufacturer's instructions (set out in the Information for Users attached as Appendices 1, 2, and 3).
  - a clear process to be followed referring those with positive or indeterminate/invalid test results for a follow-up PCR test.
  - that the tests are only for use in individuals who are asymptomatic for COVID-19.
  - that the use of a rapid antigen test does not override any public health advice that would require an individual to get a PCR test.
  - that the organisation will have clear supply chain management and recording of test kits, including batch numbers, to facilitate recalls and any checks on the integrity of the products.
  - that the organisation will have a clear process for recording test frequency, results, and the test history of individuals.
- Inform Healthline when there is a positive result as soon as reasonably practicable and seek urgent advice from the closest GP or urgent care clinic.
- Support and enable employees and contractors in standing down from work in order to get a PCR test following a positive rapid antigen test result.
- Allow employees to take paid sick leave or paid special leave if they do return a positive or indeterminate/invalid rapid antigen test result, to enable them to self-isolate while waiting for the outcome of a PCR test.
- Agree that where an employee is symptomatic, they will be advised to get a PCR test immediately rather than use a rapid antigen test.
- Agree that where a rapid antigen test result is indeterminate, invalid, or positive, that a person will go get a PCR test.
- Provide employees and contractors with information on their rights, including whether or not the use of a rapid antigen test is compulsory or voluntary, and what will happen if they do not use them.
- Support government agencies in creating guidance for their websites and, lessons learned for future phases.
- Only import and use rapid antigen tests approved by MOH.
- Only use rapid antigen tests for the purposes of the trial.
- Not onsell any rapid antigen tests.
- MOH, MBIE, and businesses are responsible for their own costs in relation to this trial.
  - The New Zealand Government will not pay for the tests or the importation of tests for the avoidance of doubt.
- Each organisation has a number of trained staff who oversee or administer tests. These staff must either a) be a registered medical professional or b) have received training from a registered medical professional or the manufacturer on the specific tests in use in the organisation.
  - Training will include, but is not limited to:
    - *How to administer the specific tests*
    - *Common issues or errors in test administration*
    - *Record keeping for supply chain management and records of test results*
    - *Referral and escalation requirements for positive, invalid, or indeterminate results*
    - *The Health Information Privacy Code*
    - *Infection Prevention and Control*
    - *Safe disposal of test kits*

- Provide an agreed anonymised dataset to MBIE and MOH for reporting purposes on a weekly basis, including:
    - *Total number of rapid antigen tests.*
    - *Number of positive results.*
    - *Number of indeterminate results.*
    - *Number of invalid tests.*
- Attend meetings (as requested by MBIE) but not to exceed weekly to report back on lessons learned, including:
    - *how the rapid antigen tests are used in practice*
    - *whether there are any impacts on operations, and*
    - *whether there has been a behaviour change in the workforce since introducing rapid antigen tests e.g. amount of sick leave taken, perception of Covid-19 risk, willingness to undergo PCR tests.*

List of businesses:

Mainfreight,
Foodstuffs North Island,
Genesis,
Hynds Pipe Systems,
Mercury,
Summerset Group,
Wellington Airport,
Christchurch Airport,
Sky NZ,
Queenstown Airport,
Spark,
Vodafone,
The Warehouse Group,
ANZ Bank,
Contact Energy,
Fulton Hogan,
Woolworths NZ,
Fletcher Building,
Chorus, Carter
Holt Harvey,
Meridian Energy,
DHL Express NZ,
Air NZ and
Auckland Airport.
Silver Fern Farms
Turners and Growers

Appendix 2

SOP024 - Covid
Saliva Rapid Antigen

Appendix 3

Mainfreight - Test
Result Interpretation &

SAFE OPERATING PROCEDURE

Saliva Covid Rapid Antigen Testing

This Protective Equipment **MUST BE WORN**	See depiction at the end of this SOP	This Protective Equipment **MAY BE REQUIRED:**	

Associated Risk Assessment No

Purpose – To ensure that team members undertaking Saliva Covid Rapid Antigen Testing can do so safely and avoid becoming infected with Covid-19.

Scope - Training - All team members who undertake this task must review the safe operating procedure and sign off on the last page.

Definitions

Covid 19 – A highly infectious respiratory and systemic illness caused by exposure to aerosols or airborne droplets containing Covid – 19 Corona virus particles.
Saliva Rapid Antigen Test Kit – A test kit intended for the qualitative detection of the antigen of the SARS-CoV-2 in human saliva samples.
Positive Test Result – The saliva rapid antigen test kit has indicated that the team member may have Covid 19
Negative Test Result – The saliva rapid antigen test kit has indicated the team member doesn't have Covid 19.
Invalid Test Result – The saliva rapid antigen test kit has been used incorrectly giving a null and void result.

Responsibilities & Authorities:

Management – It is the responsibility of Management to provide appropriate and safe equipment and the necessary safe systems of work.

Mainfreight testing team members– Must be trained in how to conduct a saliva rapid antigen test so that the test result is accurate. The team members are to employ hygienic techniques to avoid contracting Covid 19 off any potentially positive team members. Team members conducting testing must ensure that the SOP is followed in a safe manner and do not endanger themselves or other team members.

Team members being tested must:

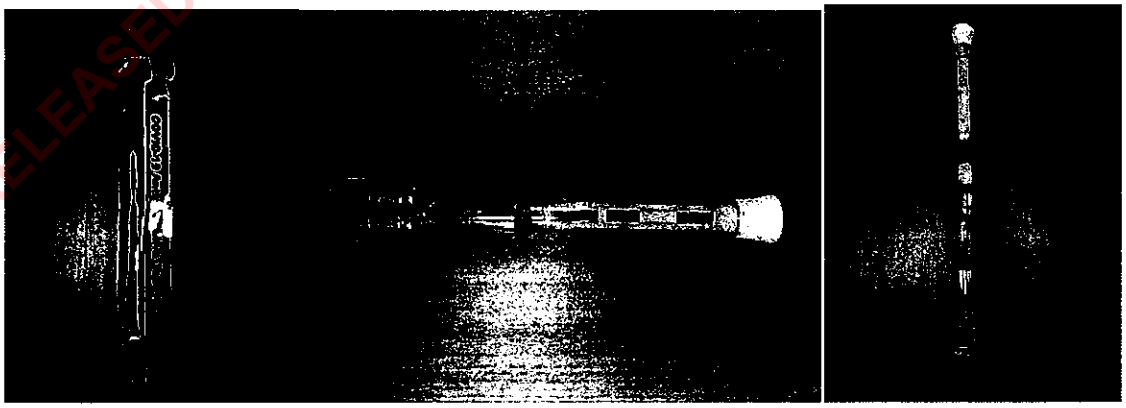
- Adhere to saliva rapid antigen testing process and all safety protocols built into that process.
- Follow the instructions of the Mainfreight team member in charge of the saliva rapid antigen testing process.

	Task
1.	**Important Information (pre-start)** • Team members conducting the saliva rapid antigen testing must be on site and ready to commence 30 minutes before the start of each shift. • Testing team must be tested and have a negative result before commencing testing other team members. • Team members must be dressed in the required PPE before commencing testing. • Team members must ensure they have sufficient test kits available for the expected number of tests to be conducted. • Team members must ensure they have sufficient stocks of PPE available for use prior to the commencement of testing.

2.	**Site Safety Checks** Team members conducting testing are to inspect the area they will be using and ensure: o The area is free of ground obstacles. o Systems are in place to ensure traffic can move safely. o Sufficient protection is in place to protect the team from variations in the weather. o Sufficient light is available to undertake the task. o The team member being tested **must not exit the car** at any stage during testing. o All testing team members are monitored for fatigue during the testing process, especially those team members who have been testing the early shift.
3.	**Front Gate Team Member** • Team member being tested arrives at the front gate in their car. • Team member being tested is to remain in their car. • Team member being tested must have not eaten food, drunk liquid, smoked or cleaned their teeth for 30 for minutes prior to undertaking the rapid antigen test. • The Gate team Member will ask the team member being tested if they have any flu like symptoms. If the team member does have symptoms, they are to be directed to the nearest Covid testing station for a PCR Covid test. • The Gate Team Member will use their phone to log into the CMS website and check that the team member being tested has made an appointment. If an appointment has been made the team member being tested is checked in. • If the team member being tested has not made an appointment, the team member being tested is given a QR code to scan. This will take the team member to the CMS website where they can enter their details and make an appointment. Note the team member being tested may need direction from the Gate Team Member to assist with completing this task. • The Gate Team Member will hand the team member being tested the instruction sheet and the test kit. The Gate Team Member is to read through and explain the instructions for using the test kit to the team member being tested. • The Gate Team Member will direct the team member being tested to the Traffic Control Team Member.
4.	**Traffic Controller Team Member Initial Set Up** • Traffic Control Team Member will direct the car the team member being tested is driving into a suitable parking bay. • Traffic Control Team Member will remind the team member being tested on how to use the rapid antigen test kit. • The Traffic Control Team Member will authorize the team member being tested to open the test kit package and commence the test. • The team member being tested is to start timing the test process on their mobile phone once they have begun the test procedure.

5. Testing Procedure

- Team members being tested must not eat/drink/smoke/clean teeth/chew gum for 30 minutes prior to being tested. Water is OK.
- Team member being tested is to cough four times and move tongue around to ensure there is enough saliva available for the test. Mask must not be removed during this step.
- Team member being tested is to remove the test kit from the plastic bag.
- Team member being tested removes the holding cap from the test unit and places it vertically on the dashboard of the team members vehicle. Team member can remove their mask
- Team member being tested removes the plastic cover from the saliva swab end of the test kit and places the swab on the back of the tongue. If there is not enough saliva, move the swab around the mouth to generate more saliva. The team member being tested must not suck or chew on the test stick while in the mouth.
- Close the mouth round the test kit and breath through the nose. Keep the test in the mouth for two minutes.
- After two minutes have elapsed, push the saliva end of the test kit into the holder cap until an audible click is heard and stand vertically on the car dashboard. The saliva swab must sit in the holder for 15 minutes. The team member being tested must not leave the car during this 15-minute period.
- After the 15-minute interval has elapsed, the team member being tested is to turn on the car hazard lights to indicate to the Traffic Control Team Member that the 15-minute analysis time has been completed.

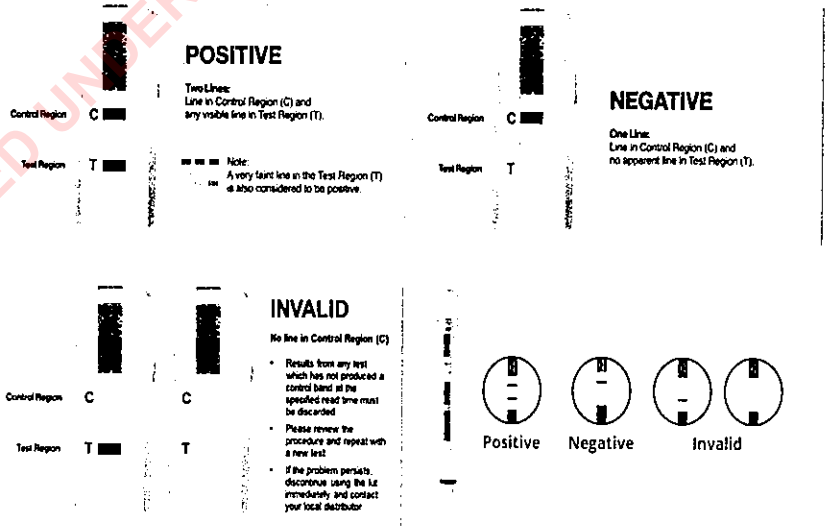


6. Traffic Control Team Member Post Test

- Traffic Control Team Member to go to the team member who has completed the testing process and confirm if the test is positive or negative.
- Traffic Control Team Member now enters the result on the CMS website for the team member who has just been tested.
- At no point are members of the Mainfreight testing team to handle the used test equipment.
- If the test result is negative, the team member who has been tested can exit their car, dispose of all testing equipment in the bio-waste bin and commence their normal shift.
- If the test result is positive, the team member who has been tested must stay in their car and repeat the test 15 minutes later. If a second positive result if obtained, the team member being tested must:

1. Contact the CMS Medical Support Hotline on 1300 588 506
2. State their full name as per their Medicare Card, their employer (Mainfreight) and that they have been instructed obtain a PCR swab text following a positive Saliva Rapid Antigen Test at work
3. A CMS telehealth nurse will subsequently organise for a pathology request form to be sent to the team member to enable Covid PCR testing at the nearest testing location.
4. Team member who has tested positive must call their Branch Manager and advise of the positive result. The team member conducting the testing must also advise the relevant Branch Manager.
5. Leave the site as soon as they have finished liaising with CMS.

TEST RESULTS INTERPRETATION



7. Personal Protective Equipment (PPE) and Other Equipment

The minimum required PPE is

- Nitrile gloves. Gloves to be changed a minimum of every hour or if a positive result is obtained. Gloves should be changed sooner if the gloves have become sweaty. Used gloves to be placed in the bio-waste bin.
- Surgical mask. Mask to be changed a minimum of every hour or if a positive result is obtained. Used masks to be placed in the bio-waste bin.
- Bio waste bin.

If deemed necessary, the below optional PPE can be utilised.

- P2/N95 Filter mask. If used, P2/N95 masks are to be changed a minimum of every hour or if a positive result is obtained. Used masks to be placed in the bio-waste bin.
- Plastic gown. If used, plastic gowns are to be disposed of in the bio-waste bin at the end of each shift.
- Plastic face shield. If used, face shields are to be changed at the end of each shift and sanitized before reusing.

References

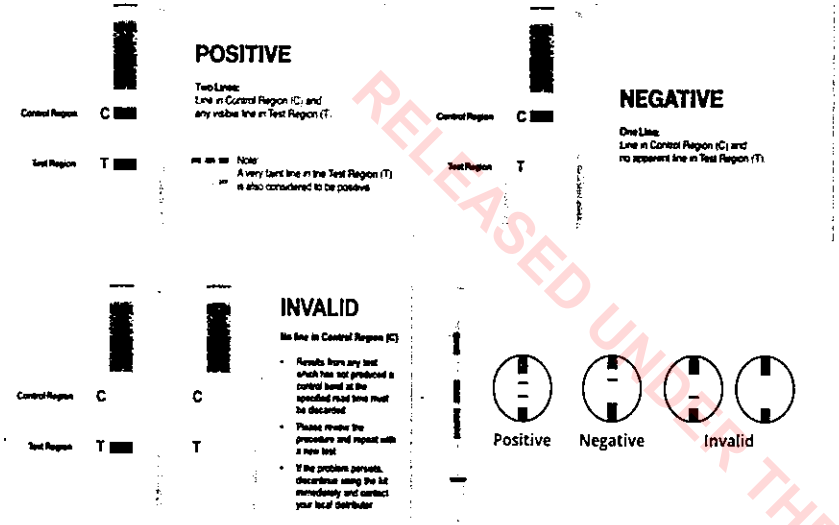
SAFE OPERATING PROCEDURE

Saliva Covid Rapid Antigen Testing

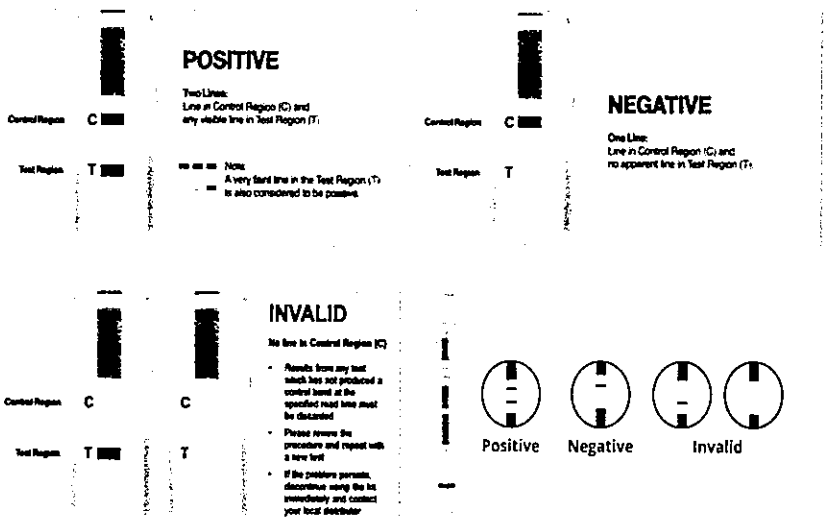
SUMMARY: COMPETENCY SIGN OFF

Employee Name *please print*	Employee Signature	Supervisor Name / Signature	Date

TEST RESULTS INTERPRETATION



TEST RESULTS INTERPRETATION



<u>For a Positive Test once confirmed please follow the below instructions.</u>

- Contact CMS Medical Support hotline 1300 588 506.
- State your Full Name as per Medicare, Employer (Mainfreight) and that you been instructed to obtain a PCR swab test following a positive Rapid Antigen Test at work
- A telehealth nurse will subsequently organise for a pathology request form to be sent to you to get tested at the nearest testing location.
- You will need to leave site as soon as this is completed and complete a PCR swab test

<u>For a Positive Test once confirmed please follow the below instructions.</u>

- Contact CMS Medical Support hotline 1300 588 506.
- State your Full Name as per Medicare, Employer (Mainfreight) and that you been instructed to obtain a PCR swab test following a positive Rapid Antigen Test at work
- A telehealth nurse will subsequently organise for a pathology request form to be sent to you to get tested at the nearest testing location.
- You will need to leave site as soon as this is completed and complete a PCR swab test

MINISTRY OF HEALTH
MANATŪ HAUORA

Memo

Seeking an authorisation for one organisation under the COVID-19 Public Health Response (Point-of-care Tests) Order 2021

Date:	18 October 2021
To:	Dr Ashley Bloomfield, Director-General of Health
From:	Darryl Carpenter, Group Manager – Testing and Supply
For your:	Action

Purpose of report

1. The purpose of this report is to seek authorisations under the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 (the order) for one organisation to import and supply point-of-care rapid antigen tests (RATs) for SARS-CoV-2 or COVID-19.

Background and context

2. The COVID-19 Public Health Response (Point-of-care Tests) Order 2021 came into force on 22 April 2021, replacing the Notice Under Section 37 of the Medicines Act 1981 (Gazette 2020-go1737)
3. This Order prohibits a person from importing, manufacturing, supplying, selling, packing, or using a point-of-care test for SARS-CoV-2 or COVID-19 unless the Director-General of Health has:
    a. authorised the person's activity; or
    b. exempted the point-of-care test from the prohibition.
4. The intent of the Order is to prevent testing for COVID-19 using unverified or unaccredited methods or tools and prevent the misinterpretation of any results.

Authorisation is sought for one organisation wishing to import and supply point of care rapid antigen tests to the twenty-nine businesses signed up to the MBIE Business Charter

5. This Order had the known effect of effectively prohibiting point of care testing devices and consumables for COVID-19 testing. This memo seeks authorisation consistent with section 8 of the Order for EBOS Group Ltd. to import and supply authorised point-of-care rapid antigen tests to (*and only to*) the twenty-nine businesses signed up to the Business Charter owned by the Ministry of Business, Innovation, and Employment (MBIE).

6. Without authorisation, the relevant testing devices imported by EBOS will be seized by Customs upon arrival in New Zealand and the business organisations signed up to the Business Charter will not be able to use point-of-care rapid antigen tests as intended.

7. EBOS has over 90 years of experience providing health products, including diagnostic products across New Zealand. It has extensive experience supplying within the Australian and New Zealand regulatory environment and has been working closely with the Ministry of Health to facilitate the roll out of the COVID-19 vaccine across the country. EBOS currently imports RATs for distribution to businesses undertaking tests within Australia. This existing experience with RATs, alongside active engagement with MBIE to understand the criteria of the RAT trial, gives us confidence that EBOS will manage and control import and distribution within the existing authorisations provided by the Director-General of Health. EBOS is ISO certified, with its Quality Management System conforming to AS/NZS ISO:9001:2008. This is reviewed annually.

8. The Business Charter defines the scope, purpose, and requirements of the initial phase of use of RATs by business organisations.

9. The Ministry of Health will provide guidance on operational protocols and requirements for reporting on use of RATs and reporting of results, including follow up and mandatory reporting of positive results.

10. Regular meetings and reporting mechanisms will be established between MBIE and the Ministry to monitor and learn from the initial phase of RAT use by businesses.

11. On 13 October 2021 you approved authorisation of the twenty-nine businesses signed up to the Business Charter to use the following authorised point-of-care RATs:

Point-of-care rapid antigen test
SARS-CoV-2 Rapid Antigen Test (SD Biosensor) (Nasal)
PanBio COVID-19 Ag Rapid (Nasal)
CareStart COVID-19 Antigen (Nasal)

12. The point-of-care RATs EBOS is seeking authorisation to import and supply the same authorised point-of-care RATs listed above.

13. The number of brands of RAT on this list may be increased over time, and authorisation of additional brands will be the subject of subsequent memos.

14. On 20 August 2021 you authorised the following suppliers to import and supply the named tests for the Ministry of Health Testing and Supply Group:

Supplier Name	**Point-of-care rapid antigen test**
Roche Diagnostics NZ Ltd	SARS-CoV-2 Rapid Antigen Test (SD Biosensor) (Nasal)
Abbott Rapid Diagnostics	PanBio COVID-19 Ag Rapid (Nasal)
Pantonic Health	CareStart COVID-19 Antigen (Nasal)

15. On 16 September 2021, you authorised the named suppliers (in the table above) to import and supply the named tests for organisations *other than* the Ministry of Health Testing and Supply Group. Your authorisation was, however. approved pending advice (or confirmation of advice) from the COVID-19 Testing Technical Advisory Group (CT-TAG) that these tests are

sufficiently sensitive and specific. This advice, or confirmation of advice has yet to be received but is expected this week.

16. The authorisation of EBOS will not be acted upon until the CT-TAG advice as per point 14 is received.

Recommendations

It is recommended that you:

1.	Note	The known effect the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 had of effectively prohibiting point-of-care testing devices and consumables.	Yes/No
2.	Approve	The authorisation of EBOS Group Ltd. to import and supply the named point-of-care rapid antigen tests to the twenty-nine businesses signed up to the MBIE Business Charter under the COVID-19 Public Health Response (Point-of-care Tests) Order 2021, pending the advice sought from the COVID-19 Testing Technical Advisory Group (CT-TAG).	Yes/No

Signature _____ Date: 20/10/21

Dr Ashley Bloomfield

Director-General of Health

MINISTRY OF HEALTH
MANATŪ HAUORA

Memo

Gazetting Notice: Point-of-Care Test Authorisations

Date:	10 November 2021
To:	Dr Ashley Bloomfield, Director-General of Health
Copy to:	Bridget White, DCE, COVID-19 Health System Response Olivia Payne, Senior Solicitor, Health Legal Sam Lockyer, Senior Policy Advisor, System Strategy and Policy
From:	Darryl Carpenter, Group Manager, COVID-19 Testing and Supply
For your:	Action

Purpose

1. To seek your approval to gazette multiple authorisations and exemptions for point-of-care tests pursuant to clause 10 of the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 (the Order).

Background and context

2. In order to assist with the operationalisation of point-of-care tests within Aotearoa New Zealand, a number of pilot projects are being conducted.

3. Once these pilots are concluded the use of point-of-care tests will be incrementally expanded to wider audiences. To be included in the pilots and subsequent expansions, an authorisation from yourself must be given. This process is facilitated by the National Laboratory Testing team within the COVID-19 Testing and Supply Group. Additional control measures outside of legislative controls will be implemented on a case-by-cases basis through authorisation requests.

4. Section 10 of the Order requires that the Director-General gazette any authorisations given to import, supply, sell and use point-of-care tests (section 8) as well as any point-of-care tests that are exempt from the Order (section 9). Appendix 1 sets out the gazette notice for laboratories, agencies and organisations as well as the exempted point-of-care tests you have previously authorised.

Next Steps

5. It is requested that you approve the gazette notice in Appendix 1 of this document.

6. Once approved, Appendix 1 will be submitted to the New Zealand Gazette for publishing.

Recommendations

It is recommended that you:

1.	Note	That clause 10 of the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 requires the Director-General of Health to gazette authorisation for import, manufacture, supply, sell and use of point-of-care tests; and for all point-of-care tests exempt from the Order	Noted
2.	Note	That subsequent authorisations will be sought and gazette notices will be submitted as the point-of-care testing programme progresses through its phased implementation	Noted
3.	Approve	The gazette notice in Appendix 1	Yes/No
4.	Note	That Appendix 1 will be published as soon as practicable	Noted
5.	Note	This memo will be provided to the offices of the Minister of COVID-19 Response and the Minister of MBIE	Noted

Signature _____ Date: 10/11/21

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

MINISTRY OF HEALTH
MANATŪ HAUORA

Appendix 1 – Gazetting Notice for Phase 1 of Point-of-Care Testing Programme

Pursuant to clause 8 of the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 ("Order"), I, as the Director-General of Health, hereby specify the following persons or class of persons to import, supply and sell point-of-care tests for COVID-19 for the purposes of clause 8 of the Order:

Name of company	***New Zealand Business Number***
Roche Diagnostics NZ Ltd	9429039820518
Abbott Rapid Diagnostics	9429032718850
Pantonic Health (Australia) or Arrotex Pharmaceuticals (NZ) Limited	9429041542033
EBOS Group Ltd	94290319988404
Ministry of Health	9429000082440

Pursuant to clause 8 of the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 ("Order"), I, as the Director-General of Health, hereby specify the following persons or class of persons to use point-of-care tests for COVID-19 for the purposes of clause 8 of the Order:

1. All laboratories accredited by International Accreditation New Zealand (IANZ) to ISO 15189 for COVID-19 testing, and providing laboratory testing services to District Health Boards.
2. All NZ District Health Board hospitals.
3 New Zealand Medical Assistance Team (NZMAT).
4. All signatory businesses to the Ministry of Business, Innovation and Employment Business Charter.
5. New Zealand Police.
6. Department of Corrections.

Pursuant to clause 9 of the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 ("Order"), I, as the Director-General of Health, hereby specify the following point-of-care tests or class of point-of-care tests that are exempt from clause 7(b) of the Order:

Product name	***Manufacturer***	***Product Code***
SARS-CoV-2 Rapid Antigen Test (SD Biosensor) (Nasal)	SD Biosensor (South Korea)	09365397043
PanBio COVID-19 Ag Rapid (Nasal)	Abbott Rapid Diagnostics Jena GmbH (Germany)	41FK11
CareStart COVID-19 Antigen (Nasal)	Access Bio Inc (United States of America)	7006576

Approved 10/11/24