MINISTRY OF HEALTH
MANATŪ HAUORA

Memorandum

Evaluation of a new rapid testing option for COVID-19

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To:	Hon Chris Hipkins, Minister of Health		
Copy to:	Rt Hon Jacinda Ardern, Prime Minister		

Contact for telephone discussion

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Action for Private Secretaries

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Evaluation of a new rapid testing option for COVID-19

Purpose of report

1. The purpose of this memo is to provide information regarding the evaluation of a rapid testing option for use in a New Zealand context.

Background

2. The Access to COVID-19 Tools (ACT) Accelerator was launched at the end of April 2020, as a global collaboration to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines. The ACT Accelerator brings together governments, scientists, businesses, civil society, and philanthropists and global health organizations (including the Bill & Melinda Gates Foundation, CEPI, FIND, Gavi, The Global Fund, Unitaid, Wellcome, the WHO, and the World Bank).

3. This week, the ACT Accelerator announced a global partnership to make available 120 million affordable, quality COVID-19 rapid tests for low- and middle-income countries (LMICs).

4. The rapid tests in the announcement are different that the current testing available in New Zealand in a few key ways:

   a. The most common test available in New Zealand is a polymerase-chain reaction (PCR) test, which is a molecular test with a sample taken via a nasopharyngeal swab. A test result is generally returned within a day (depending on laboratory volumes) and is a highly accurate test that diagnoses active infection.

   b. The rapid tests in the announcement are antigen rapid diagnostic tests (Ag RDTs) with a sample taken via a nasopharyngeal swab. A test result is generally returned within an hour, and it diagnoses active infection. Positive results are usually highly accurate but negative results may need to be confirmed with a molecular test, and so they can't be used to definitively rule out active infection.

5. The Bill & Melinda Gates Foundation have executed separate volume guarantee agreements with rapid diagnostic test (RDT) producers Abbott and SD Biosensor. These two arrangements will make available to LMICs 120 Ag RDTs – priced at a maximum of US$5 per unit – over a period of six months. These tests provide results in 10 to 30 minutes, rather than hours or days, and will enable expansion of testing, particularly in countries that do not have extensive laboratory facilities or trained health workers to implement molecular PCR tests.

Evaluation of these tests in a New Zealand context

6. The Abbott Panbio COVID-19 rapid test device is an in vitro diagnostic rapid test for the detection of SARS-CoV-2. The test provides preliminary results – a negative result does not preclude SARS-CoV-2 infection. The test provides a result in 10 to 20 minutes.

7. The SD Biosensor Standard Q COVID-19 antigen test is a rapid chromatic immunoassay that uses nasopharyngeal specimens, providing results in 15 to 30 minutes. It is not stated whether a negative test precludes SARS-CoV-2 infection, however we assume this to be the case based on previous evaluation experience of these types of tests.

8. While these tests can provide confirmation of a positive result, they may produce a false negative, and therefore they cannot be used as the sole basis for treatment or other management decisions.

Validation of tests

9. Abbott's Binax Now antigen test has received FDA emergency use authorisation (which we know is not the result of a rigorous evaluation of test performance), but they are not marketing it outside the United States. They are instead marketing their PanBio antigen test in Europe, Australia and New Zealand. The two Abbott tests are considered comparable.

10. ESR have been in contact with Abbott who are keen for their PanBio antigen assay to be evaluated in New Zealand. Unfortunately, like the South Korean Ag RDT (SD Biosensor), there is no published performance data, or any post marketing validation reports available.

11. ESR have sought Abbott's own performance data however have only received the instructions for use. Abbott have also not provided any information about how the PanBio assay compares in terms of performance to their Binax Now assay. It is therefore currently impossible to evaluate the sensitivity and specificity of the two assays in the ACT Accelerator announcement. We are continuing to follow-up on this information.

12. In addition, both the Abbot and BioSensor assays require their own specific nasopharyngeal swab. In order to evaluate them ESR advises we would need to ask patients to have two nasopharyngeal swabs taken at the same time, one for PCR and for the antigen test validation. Given their invasive nature, individuals may not be comfortable with a second swab being taken.

Use case for tests

13. The tests in the ACT Accelerator announcement (see paragraph 2) are specific but are not very sensitive and as such are likely to miss some cases, especially where the prevalence of COVID-19 is low in the community, as is the case in New Zealand. Similar rapid antigen tests have shown a lower sensitivity than rapid PCR tests and been previously rejected for use in New Zealand.

14. WHO guidance highlights the value of these tests in areas where community transmission is widespread and where PCR testing is either unavailable or where test results are significantly delayed, which is not the case in New Zealand. As well as supporting test-trace-isolate strategies, the tests can help identify or confirm new outbreaks, support outbreak investigations through screening, and monitor disease trends. The advantage is that they give a result quickly allowing the individual to be isolated and stop the chain of transmission.

15. As we have a very low risk of community transmission in New Zealand, and good availability of PCR tests with relatively quick turnaround times, there is limited value in deploying these tests widely in New Zealand at this time.

Next steps

16. The Ministry continues to monitor new developments of rapid testing and are working with ESR to progress the validation of new testing techniques and products. As part of this the Ministry and ESR are monitoring:

    a. under what circumstances would a rapid antigen test be useful in the ongoing management of COVID-19

    b. what performance metrics (including sensitivity and specificity) would be acceptable

    c. whether it would be justified to confirm a rapid test result (either positive of negative) by taking a second nasopharyngeal swab.

    d. costs and availability of these tests.

17. We will keep you informed of progress in this space.

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