Briefing

Further advice on the use of rapid antigen tests

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To:	Hon Chris Hipkins, Minister for COVID-19 Response		

Contact for telephone discussion

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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☐ See Minister's Notes ☐ Withdrawn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 advice on the use of rapid antigen tests

Background

1. Antigen tests detect the products of viral replication, most commonly viral encoded proteins. As indicated in previous advice from the Ministry of Health (the Ministry), many antigen tests will generally identify acute infection during the early stages when the viral load is highest, however may miss infections where there is a low viral load (HR20210494 refers).

2. Further review of available evidence regarding rapid antigen tests has been carried out by the Ministry, and an assessment of their suitability for use in our current context.

Recommendations from other jurisdictions

3. The World Health Organisation (WHO) recommends that, to be considered for use, rapid antigen tests should meet certain criteria (≥80% sensitivity and ≥97% specificity compared to an approved nucleic acid amplification test (NAAT)) in a situation where NAAT is unavailable or the health system is overburdened, leading to prolonged turnaround times (above 48-72 hours). RT-PCR tests as used for COVID-19 testing in New Zealand is a type of NAAT.

4. In New Zealand the vast majority of PCR tests results are returned within 24 hours.

5. In addition, the WHO recommends that rapid antigen tests should not be used where there are sporadic or no cases nor for airport/border screening at points of entry or prior to travel unless all positive results can be confirmed by RT-PCR. Moreover, the sensitivity of any test will be lower in asymptomatic infection reflecting the lower viral loads.

Information from the literature

6. A Cochrane review of rapid antigen tests for the diagnosis of SARS-CoV-2 infection found an average sensitivity of 68.9% (95%CI: 61.8% to 75.1%) and average specificity of 99.6% (99.0% to 99.8%) from 51 evaluations (21,614 samples).

7. Sensitivity was higher for symptomatic patients (72.0%, 95% CI 63.7–79.0%) than for asymptomatic patients (58.1%, 95% CI 40.2–74.1%) and was higher during the first week after the onset of symptoms (78.3%, 95% CI 71.1–84.1%) compared to the second week (51.0%, 95% CI 40.8–61.0%).

8. A recent study from the United Kingdom, not included in the Cochrane review, reported that 60% of asymptomatic infected people were not detected by a rapid antigen test i.e., a very low 40% sensitivity (95%CI: 28.5% to 52.4%).

New Zealand based studies

9. The Institute of Environmental Science and Research (ESR) conducted an evaluation of five rapid antigen tests and found an average sensitivity of 36.8% (95%CI: 30.3% to 43.9%) with no significant difference between the individual test kits.

10. The study authors concluded that the rapid antigen tests evaluated did not reliably detect the SARS-CoV-2 virus when the Ct value was >28-30 (i.e. late in infection or low viral load present) and that even though these tests offer a simpler and cheaper approach to testing, they lack the necessary sensitivity to replace RT-PCR.

Clinical application

11. The clinical utility of rapid antigen tests is difficult to assess in a low prevalence setting such as New Zealand. The sensitivity of rapid antigen tests are consistently lower than RT-PCR as evidence in international literature. The local ESR study which evaluated 5 test kits varied in their sensitivity depending upon the presence (or not) of symptoms and the timing of the test with respect to disease onset.

12. In a setting of low prevalence of COVID-19 and with elimination strategy as exists in New Zealand, there is no evidence to support the replacement of PCR tests with rapid antigen tests for the detection of SARS-CoV-2 due to the low sensitivity resulting in an inability to reliably identify potentially infectious individuals.

13. The primary advantage of rapid antigen tests is the ability of the test to identify positive case within a very short time frame. Many international airports are offering rapid antigen tests so that customers can be tested before they travel. Schools in the United Kingdom have been undertaking rapid tests on students. However, these are operating in contexts where there is high prevalence of COVID-19, and where a missed positive case has little to no impact that countries response strategy overall.

14. New rapid antigen testing devices continue to become available to the market. For example, we are aware of an Australian-made testing device that has recently been given Therapeutic Goods Administration approval – however the manufacturer recommends that they are not used in low-prevalence environments. If a suitably sensitive test does become available, further consideration will be given to its use in New Zealand.

Next steps

15. Additional advice on the usefulness of rapid antigen testing is being explored as part of the future testing arrangements at the border.

16. A report with scenarios of potential utilisation of rapid antigen testing at the border will be provided by early September 2021.

Recommendations

We recommend you:

a) **Note** that rapid antigen tests for COVID-19 have significantly lower sensitivity than RT-PCR tests. **Yes/No**

b) **Note** that the likelihood of missed infections makes rapid antigen tests unsuited for use in New Zealand at present where there is a low prevalence of COVID-19 and a single missed infection can have a significant impact on the success of the elimination strategy. **Yes/No**

c) **Note** that additional advice on the utilisation of rapid antigen testing is being explored and will be reported back by early September 2021. **Yes/No**

Shona Meyrick
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COVID-19 Health System Response
Date: 2 August 2021

Hon Chris Hipkins
Minister for COVID-19 Response
Date: