MINISTRY OF HEALTH
MANATŪ HAUORA

Memorandum

Saliva testing for COVID-19 in New Zealand

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To:	Hon Chris Hipkins, Minister for COVID-19 Response		
Copy to:	Hon Dr Ayesha Verrall, Associate Minister of Health		

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Action for Private Secretaries

Date dispatched to MO:

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Saliva testing for COVID-19 in New Zealand

Purpose

1. The purpose of this memo is to provide an update on a meeting held between the Ministry of Health (the Ministry) and Rako Science on 18 February 2021, and the potential implications for the roll out of saliva testing in New Zealand.

Background

2. Saliva testing is a common label for COVID-19 PCR testing that is performed using a saliva sample. Our current diagnostic test for COVID-19 is a PCR test using a nasopharyngeal swab.

3. The Ministry commenced voluntary saliva testing of staff at the Auckland quarantine facility on 25 January 2021. This was subsequently paused to ensure focus on testing in response to individuals testing positive for COIVD-19 after completing managed isolation at the Pullman Hotel.

4. Saliva testing recommenced on 9 February 2021 at the Auckland quarantine facility and commenced at one of the dual-use facilities in Christchurch in the same week. Wellington has now also commenced saliva collections in its dual-use facility.

5. This testing is being carried out by Middlemore, Wellington SCL and Canterbury Health Laboratory. These laboratories have completed technical validation of the RT- PCR assays in use to test the saliva samples and have either achieved or are working through the requirements for IANZ accreditation of this test as a surveillance test.

6. As at 17 February 2021, 160 saliva tests had been completed.

7. On 15 February 2021 Auckland Airport issued a press release stating that they had partnered privately, and separate to the rollout by the Ministry, with Rako Science to deploy saliva testing for COVID-19 for their staff. Rako Science has established COVID-19 surveillance testing in New Zealand using the SHIELD saliva test developed at the University of Illinois.

8. Rako Science has claimed that their saliva tests are as sensitive as PCR tests that are performed on nasopharyngeal swabs.

9. Auckland Airport is co-funding the deployment and has set up a dedicated space for testing. Airport staff taking part in the saliva tests are doing so on a voluntary basis and the saliva tests do not replace the nasopharyngeal swabs required as part of the public health response in New Zealand.

10. This deployment of saliva testing was done independently of the Ministry.

11. We are aware of other organisations who are working towards rolling out saliva testing. Hills Laboratories have commenced saliva testing for aged residential care staff, and Ryman Healthcare have issued a press release regarding their work with Hills Laboratories.

12. The key difference between this and Rako Science is that Hills Laboratories test is not accredited by IANZ, and they are using the saliva direct method (a protocol developed by the Yale School of Public Health that can be used on a range existing assays, and has received Emergency Use Authorization (EUA) from the US Food and Drug Administration).

The Ministry met with Rako Science on 18 February 2020

13. Officials from the Ministry, scientists from ESR and a microbiologist from ADHB met with Rako Science and others who have supported the roll out including:

    a. Stephen Grice (Founder – Rako Science)

    b. Martin Burke (May and Ving Lee Professor for Chemical Innovation, and Professor of Chemistry – University of Illinois)

    c. Janet Pitman (Associate Professor – Victoria University),

    d. Amanda Dixon-McIvor (Laboratory Director – IGENZ, the laboratory contracted to Rako Science, which has been accredited by IANZ),

    e. Arthur Morris (Clinical Microbiologist and Consultant Pathologist)

14. Overall, the meeting was a productive discussion, heavily centred on the science behind the testing, and the clinical studies carried out by the University of Illinois which are the basis of Rako Science's confidence in the test.

15. In summary, the University of Illinois confirmed:

    a. a clinical study (currently un-published and not peer reviewed) of symptomatic patients showed that 97% of positive COVID-19 cases tested positive with the saliva test, and 99% of negative COVID-19 cases tested negative with the saliva test

    b. that when they rolled out the saliva testing at scale on their campus, false positivity had not been an issue

    c. nil by mouth (not eating, drinking, smoking, or chewing gum) for 30 minutes before the test was critically important and caused issues with some samples – when they increased the requirement to 60 minutes, the issues significantly reduced

    d. that a double test is always run on a positive test – if within a test only one gene is positive (rather than two needed for a conclusive positive), it is treated as inconclusive and the patient is asked to resubmit a sample.

    e. they perform saliva testing on a twice weekly basis

16. Importantly, the University of Illinois noted that the setting of the testing is important – in their view saliva testing as surveillance testing in the workplace, for example, could be useful as there will be another test in a few days. When deployed at the University of Illinois campus, they had the benefit of regular ongoing testing. with longitudinal negative data on an individual, a weak positive carried more weight and generally indicated early infection.

17. The Ministry's expert advisors noted the following in response to the information shared by Rako Science and the University of Illinois:

a. the work that had been undertaken by the University of Illinois to develop the method was impressive and commended the Rako Science team for their validation of it in New Zealand

b. that Rako Science had done all they can to demonstrate the sensitivity of their saliva test in the absence of paired saliva and nasopharyngeal swabs

c. the validation was carried out on a small number of paired samples (35), and with saliva samples and nasal swabs, as opposed to nasopharyngeal swabs

d. the confidence intervals in the sensitivity data provided were comparatively low (around 80%)

e. for inconclusive results, in New Zealand, we could not afford to wait for the next test – there would be a need for an immediate re-test (with a nasopharyngeal swab) to ensure the risk of community outbreaks could be minimised

f. New Zealand does not operate in the same context as the University of Illinois, in that we do not have a high prevalence of positive cases, making it very difficult to validate laboratory assays – the possibility of using the University of Illinois specimens to validate New Zealand laboratory assays was raised.

18. Our technical experts have summarised their assessment – "As technical experts we were satisfied that IGENZ's assay is a sensitive and accurate test to detect SARS-CoV-2 in saliva for surveillance purposes. Given that the paired nasal saliva samples were not nasopharyngeal swabs and that the number of tests performed are too low to be statistically significant we are of the opinion that IGENZ cannot claim that their assay is as sensitive as nasopharyngeal swabs".

19. Note that IANZ, in agreement with the Ministry, accredited IGENZ to process saliva testing as a surveillance test only, given the lower sensitivity and inability to complete clinical sensitivity verification in the New Zealand setting.

20. Overall, due to the information above the Ministry and ESR do not have enough information to conclude that saliva testing is equivalent to nasopharyngeal swabs, especially in the New Zealand context. However, it is agreed that saliva testing does have some utility – especially as a surveillance test.

21. However, there remains conflicting perspectives in New Zealand and globally regarding the role of saliva testing, with experts in New Zealand reaching different conclusions for its use in the New Zealand context. It is important to recognise that the Ministry and ESR's position is supported by other respected experts, but also disagreed with by others.

22. Rako Science and the Ministry (with support from ESR) agreed to work constructively on an agreed shared position on the accuracy of saliva testing, and on the role of saliva testing as a surveillance test in New Zealand. Further discussions will be held in the coming weeks.

Implications for the rollout of saliva testing in New Zealand

23. While the conversation with Rako Science does not change the Ministry's overall direction of travel, it did indicate that they may a suitable partner to be involved in the

rollout of saliva testing as part of the public health response to COVID-19 in New Zealand at some point in the future.

24. In New Zealand using a nasopharyngeal swab is the recommended collection method for both symptomatic and asymptomatic COVID-19 testing due to its higher sensitivity in detecting the virus.

25. In New Zealand we have a very low prevalence of COVID-19 and a strategy of elimination, and therefore need the most sensitive tests to detect cases as early as possible. Countries that have large scale outbreaks can use different testing regimes and cannot be compared directly to New Zealand.

26. Despite saliva testing not yet being proven as equivalent to a nasopharyngeal, there is emerging consensus, including agreement from ESR, that saliva testing may be suitable as a surveillance test for asymptomatic cohorts. In addition, there are several potential laboratories who may be able to undertake this testing, including Rako Science, who at this stage have progressed furthest with the relevant development work.

27. In recognising that saliva testing has utility as a surveillance test, focus should shift from comparing the saliva sample to the nasopharyngeal swabs, to where and how saliva testing can best support the COVID-19 response in New Zealand.

28. Further work on the comparison can be undertaken in parallel, where previously it has been considered a prerequisite to any rollout. ESR is progressing this via a broad proposal to the Health and Disability Ethics Committee (HDEC) that will give approval to collect saliva samples from positive cases in managed isolation and quarantine facilities, both alongside their regular nasopharyngeal swab and in between their mandatory tests, on a voluntary basis. In addition, ESR are continuing to explore the possibility of importing positive paired samples.

Progressing the roll out of saliva testing in New Zealand

29. The Ministry is progressing work to assess how saliva testing could best be deployed across several dimensions:

    a. Frequency of testing - The appropriate target groups for the use of saliva associated with an increased frequency of testing. Despite the calls for daily saliva testing such as in used in some areas in Australia, the University of Illinois undertake saliva tests twice weekly. The target groups and frequency will be guided by the public health advice regarding how saliva testing can best increase the robustness of our border measures.

    b. Workforce - The collection of saliva samples if undertaken by the existing swabbing workforce would place significant pressure on an already stretched workforce. Any deployment should have a robust self-collection process or utilise an alternative workforce. Self-collection may reduce the risk to health staff.

    c. Capacity - The processing of large quantities of saliva samples would place significant pressure on many of the existing labs due to the different workflow requirements. It is also recommended that pooling is not utilised for these samples, reducing opportunities for scaling capacity. The Ministry is exploring whether partnering with other labs such as Rako Science would be a better approach than attempting to stand up duplicate testing processes in the existing lab network.

d. Consumables - The impact on lab consumables needs to be considered. Although the test assays currently in use for saliva testing are not globally constrained, many other consumables that are required for the testing such as pipettes and plasticware are globally constrained. An assessment would be required on the impact on our ability to respond in the event of a significant outbreak.

e. Cost - The cost of a saliva testing regime, particularly where saliva tests are likely to be at an increased frequency to the current testing regimes. Given that these are also laboratory-based PCR tests, it is likely the total cost will be similar to nasopharyngeal testing.

Next steps

30. Officials can provide further information about this topic at your request.

31. Advice on any deployment of saliva testing for screening purposes for border workers will be provided to Ministers in mid to late March (HR20210062 Implementation of COVID-19 saliva testing as part of border workforce testing in New Zealand refers).

Sue Gordon
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Date: