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27 November 2020

[redacted]

By email: [redacted]
Ref: H202007500

Dear [redacted]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 30 September 2020 for:

> *"The effectiveness of Covid-19 saliva tests and potential use in New Zealand*
> *Any contractual arrangements entered into for the delivery and processing of Covid-19 saliva tests*
> *Please take this request to include Cabinet and Cabinet Committee papers and minutes, reports, oral and written advice, aide memoirs, briefings, memoranda, and correspondence (including e-mails) that may be caught by the wording."*

Information within scope of this request is itemised in Appendix One of this letter and copies of the documents are enclosed. The table in Appendix One outlines the grounds under which I have decided to withhold information. Where information is withheld, this is noted in the document itself. Excerpts have been released in accordance with section 16(1)(e) of the Act, with information deemed out of scope of your request excluded.

Your request for correspondence (including emails) is refused under section 18(f) of the Act, as it would require substantial collation to provide this to you.

Auckland and Counties Manukau District Health Board laboratories are working with the Institute of Environmental Science and Research (ESR) to obtain and test saliva and nasopharyngeal swabs in parallel on their Polymerase Chain Reaction (PCR) platforms to assess the sensitivity and suitability for use in diagnostic laboratories. Initial validation using spiked saliva samples were undertaken however, paired nasopharyngeal and saliva from COVID-19 positive cases are required to fully validate this testing methodology. It will take some time before enough samples can be sourced in order to complete the validation.

Initial limitations include sample volume, more labour intensive processes to prepare the sample for testing, some difficulty with automated extraction platforms due to sample type, and sensitivity being lower overall than nasopharyngeal swabs.

There is no firm plan to implement saliva testing as laboratories are still in the process of obtaining paired nasopharyngeal swabs and saliva samples from COVID-19 patients in order to validate saliva as an alternative sample type.

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.

Please note that this response, with your personal details removed, may be published on the Ministry's website.

Yours sincerely

Dr Kelvin Watson
Group Manager, Immunisation, Testing and Supply
COVID-19 Health System Response

Appendix 1: List of documents for release

#	Date	Title	Decision on release
1	10 August 2020	Health Report (20201353): Laboratory surge capacity and alternative testing options	Excerpts released in accordance with section 16(1)(e) of the Act.
2	10 September 2020	Health Report (20201544): Update on emerging technology for testing for COVID-19	Released with some information withheld pursuant to section 9(2)(a) of the Act, to protect the privacy of natural persons.
3	16 September 2020	All of Government update from STA (Science and Technical Advisory)	Excerpts released in accordance with section 16(1)(e) of the Act.
4	18 September 2020	Health Report (20201704): Cabinet talking points- 21 September 2020	Excerpts released in accordance with section 16(1)(e) of the Act.
5	21 September 2020	Update on new technologies	Released in full.
6	2 October 2020	Health Report (20201791): Cabinet talking points: 5 October 2020	Excerpts released in accordance with section 16(1)(e) of the Act.

Excerpt from Health Report 'Laboratory surge capacity and alternative testing options'

10 August 2020

Saliva testing

14. Saliva testing as a routine option for surveillance testing remains well over a month away – laboratories are yet to validate their assays for saliva as a specimen type, and many need to adapt their current workflow processes to enable these tests to be carried out. In addition, positive patient samples are required for diagnostic laboratories to be confident with the technical aspects of the tests, and approval of validation reports from the accreditation authority will still be required.

15. To progress this, ESR will be providing laboratories with cultured inactivated samples, dependent on the laboratories having the right protections in place to make these safely. Also being explored is the possibility of sourcing saliva samples for positive control material from patients in managed quarantine facilities. Sourcing sufficient positive saliva samples to validate all laboratories and gaining the appropriate ethics approval and accreditation is likely to take around two months.

Excerpt from Document 'AoG weekly update from STA'

16 September 2020

Saliva Testing

- Testing saliva is approximately as sensitive and less invasive than NPS, but the tests have not yet been validated for use in NZ
- Validation is difficult without paired **positive** samples (concurrent saliva and nasopharyngeal swabs)
- There are technical issues with using saliva which need to be overcome

Excerpt from Health Report 'Cabinet talking points: 21 September 2020'

18 September 2020

Saliva testing technology

- Saliva testing can detect active virus and may provide an option for less invasive testing.
- ESR is progressing protocols for testing the viability of saliva testing. ESR propose to request saliva samples from the population of people who are already required to be swabbed for COVID-19 working in border settings. The Ministry is in support of ESR's work and progress in this area and is staying informed of developments of the protocol and the operational environments.
- Limitations and timeline:
    - Saliva testing is likely to provide an alternative method of sample collection and test type that will be less sensitive than nasopharyngeal PCR testing, but which could be used for screening in certain populations (such as border workers who require regular testing) rather than diagnostic purposes.

- Given the very low prevalence in New Zealand, we need to use the most sensitive test possible to ensure positive cases are identified.
- Laboratories have signalled that the processing of saliva samples is much more complex and labour intensive then current nasopharyngeal samples.
- There are also challenges in the collection of saliva samples from individuals. Many people do not provide enough saliva, and they must not eat, drink, or smoke for 30 minutes before.
- The timeline for at least one laboratory to offer a validated saliva testing service will depend on the initial comparison between NPS and saliva and how many samples can be sourced from managed quarantine facilities. ESR will support the validation process by providing spiked samples where possible.
- Saliva testing is not likely to begin in the next two months due to the scientific validation process taking some time. However, ESR continue to build evidence that the virus can be detected in saliva at suitably low levels, and with more positive saliva samples in the system we can expect the laboratory network to have a better understanding of how to handle saliva samples in the next three weeks.

Excerpt from Health Report 'Cabinet talking points: 5 October 2020'

2 October 2020

Testing

Update on saliva testing

- Work is continuing on the viability of saliva testing in New Zealand, and the earliest the saliva testing might be available at scale would be in the first quarter of 2021.
- ESR is working with Air New Zealand to design a saliva sampling study on aircrew but are yet to submit a Health and Disability Ethics Committee (HDEC) application.

The Jet Park repeat saliva sampling study has received HDEC approval, and I understand ESR is approaching Counties Manukau DHB to see if nurses at the clinic at Jet Park can perform nasopharyngeal swabbing. If they can, ESR will apply for an amendment to HDEC approval.

Document Two

MINISTRY OF HEALTH
MANATŪ HAUORA

Health Report

Update on emerging technology for testing for COVID-19

Date due to MO:	10 September 2020	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	20201544
To:	Hon Chris Hipkins, Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Sue Gordon	Deputy Chief Executive COVID-19 Response	s 9(2)(a)
Louise Chamberlain	Manager Science and Technical Advisory, COVID-19 Directorate	s 9(2)(a)

Action for Private Secretaries

Return the signed report to the Ministry of Health.

Date dispatched to MO:

Update on emerging technologies for testing for COVID-19

Purpose of report

This report provides you with:

- an update on two key emerging technologies for testing of COVID-19 (SARS-CoV-2), saliva Out of scope testing, and the stage of development of each
- information on the potential use and limitations of these emerging technologies to support current best practice.

Summary

- There is emerging technology in testing which is likely to increase options for sample collection and processing, and for testing for history of disease exposure as well as active infection. The two emerging technologies of interest described here are saliva and Out of scope testing.
- ESR, regional public health services, laboratories, and the Ministry of Health are progressing investigations in these technologies and expect to have more information on timelines in the next three to four weeks.
- Saliva and Out of scope testing will increase options in testing, but will not replace nasopharyngeal PCR testing, at least in the foreseeable future. Both technologies have limitations in their implementation and in what information on disease control can be deduced from their use, and should not be considered to be transformative in the current testing environment.

Recommendations

The Ministry recommends you:

a) **note** progress in developing saliva and Out of scope testing methodologies (including supporting technology

b) **agree** to forward this report to Hon Megan Woods, Minister of Research, Science and Innovation **Yes/No**

Sue Gordon	Hon Chris Hipkins
Deputy Chief Executive	**Minister of Health**
COVID-19 Health System Response	Date:

Update on emerging technology for testing for COVID-19

Background / context

1. There is significant progress in development of new, improved, and alternative technologies and processes of testing for COVID-19 in people. Any proposed option will need to be assessed for reliability, accuracy, utility, and limitations prior to implementation in place of existing 'gold standard' options (currently, laboratory-processed PCR samples from nasopharyngeal swabs).
2. Key features of interest in emerging technologies for testing are:
    a. reduced invasiveness of specimen collection;
    b. increased options of methods for specimen collection;
    c. reliability and validity;
    d. opportunities to identify and trace previous infection;
    e. reduced personnel and equipment needs for processing of samples;
    f. improved turnaround time for results.
3. Saliva testing can detect active virus and may provide an option for less invasive testing for screening, and serological (blood) testing can detect current or previous exposure.
4. Reference to 'rapid' or 'point-of-care' refers to the time and place of processing the sample rather than the sample type.
5. Evaluation of emerging technologies for testing as suitable and ready for implementation or scaling is a collaborative process primarily between Environmental Science and Research (ESR) and the Ministry of Health (the Ministry). Scientific evidence, international experiences, and independent expert advice are all considered in this assessment.

Viral testing - saliva

6. Saliva testing may provide a less invasive alternative to sample collection than nasopharyngeal swabbing and may also be more suitable for some populations, i.e. border workers who are required to give multiple samples. However, saliva testing would not replace nasopharyngeal swabbing for all populations, is not 'rapid' or 'point of care' technology and is likely to result in more complex laboratory processes.
7. ESR are progressing protocols for testing the viability of saliva testing. There are a number of technical stages that need to be tested, including validation and preference of laboratory assay (technical process and protocols), laboratory capacity, and sensitivity of saliva testing through "shadow testing" against nasopharyngeal tests. ESR propose to request saliva samples from the population of people who are already required to submit specimen through nasopharyngeal swabbing methods due to working in border settings and/or working or staying in Managed Isolation and Quarantine Facilities (MIQ). Testing of laboratory-based processes has started across

ESR, Auckland and Middlemore DHB laboratories, and the University of Otago, with support from laboratories across New Zealand.

8. ESR have requested support for the above test validation and laboratory process assessments from the Ministry. The Ministry is in support of progress in this area and is staying informed of developments of the protocol and the operational environments.

9. If the results of the test validation and laboratory process assessment indicate that saliva testing would be beneficial, implementation of the study could be supported through endorsement of uptake and provision of staff resources.

10. Saliva testing is likely to provide an alternative method of sample collection and test type that will be less sensitive than nasopharyngeal PCR testing, but which could be used for screening rather than diagnostic purposes.

11. Laboratories have signalled that the processing of saliva samples is much more complex and labour intensive that then current nasopharyngeal samples. These issues would need to be overcome for saliva samples to be used as a scaled alternative.

Limitations and timeline

12. Saliva testing is likely to provide an alternative method of sample collection and test type that will be less sensitive than nasopharyngeal PCR testing, but which could be used for screening rather than diagnostic purposes.

13. Laboratories have signalled that working with saliva samples is much more complex and labour intensive that then current nasopharyngeal samples. There are a range of sample collection and processing issues with saliva samples that need to be worked through before a full and detailed timeline and action plan can be given, including:

    a. Someone must not have consumed food or drink, smoked, or have chewed gum for 30 minutes prior to sample collection.

    b. Producing 2-3ml of saliva for the sample can be difficult - feedback from Melbourne is that many people do not provide enough sample.

    c. The frontend processing of saliva is much more labour intensive, and it is not yet understood how laboratories will cope with a number of samples which contain a mixture of saliva and nasopharyngeal samples.

    d. Some samples need to be diluted, however a study in Melbourne has shown that if you dilute saliva 1:1 into a buffer then the sensitivity drops to 84%.

    e. Automated extraction machines have problems if the sample is not liquid enough or if there are bubbles which affect liquid sensing.

    f. The Yale group had to modify the CDC assay to process saliva samples, and as such each assay in the network will need to be revalidated to see if there are any unforeseen problems with using saliva samples.

14. As each part of the process involves a stage gate, timeframes and a detailed action plan are difficult to determine. Implementation of saliva testing is not likely to begin in the next three months. However, the action plan for the next three to four weeks includes;

    a. Continuation of ESR saliva spiking experiments with dilutions of the SARS-CoV-2 virus to build evidence that the standard SARS-CoV-2 assay can be used to detect the virus at suitably low levels ("spiking" refers to laboratory-based introduction of

the virus into a negative, or "control" specimen). ESR have also received some paired nasopharyngeal swab (NPS) and saliva from COVID-19 positive cases in managed quarantine which will be run next week as part of further validation studies using the 'Kingfisher' and 'Prot K' extraction methods. ESR will be looking for challenges associated with using this type of sample.

b. With more positive saliva samples in the system including spiked volunteered saliva we can expect the laboratory network to have a better understanding which system can handle saliva samples in the next three weeks.

c. The timeline for at least one laboratory to offer a validated saliva testing service will depend on the initial comparison between NPS and saliva and how many samples can be sourced from managed quarantine facilities. ESR will support the validation process by providing spiked samples where possible.

15. Given the above, more will be understood in the next three to four weeks that will support the development of a detailed action plan and timeline.

Out of scope

Next steps

21. The Ministry will keep you regularly updated on progress and will provide you with a written update in the next four weeks.

Why alternative testing for COVID-19 isn't available yet

The Ministry of Health has received many requests about why we require the nasopharyngeal swabbing method in New Zealand to test for COVID-19 infection, instead of using other tests, like testing saliva or blood.

We explain more about this here to answer these questions.

The practicalities of COVID-19 testing

When testing for COVID-19, we want to find out who does and doesn't have the active disease. We use this information to manage the spread of the disease and to keep it under control. Note that there are two parts to testing; collecting the sample and processing the sample. So, there are a few practical things we need from our testing system:

- We need to be able to test lots of people as quickly as possible.
- The test must be as reliable/accurate as possible.
- The method for processing samples COVID-19 must be straightforward enough to allow standard laboratories across New Zealand to process the volume of samples required with the resources and time available.
- We need to get the results back quickly, so that decisions can be made about isolating or quarantining people and tracing their contacts.
- The testing method and equipment must be licenced and approved for use in New Zealand.
- The test must be affordable.

In New Zealand, we mostly use polymerase chain reaction (PCR) testing which requires either nasopharyngeal swabbing (taking a sample from the back of the nose) or, less commonly, oropharyngeal swabbing which takes the sample from the back of the throat. These approaches meet all of the points above. However, it is important to remember that there is no such thing as a perfect test. Each test will have advantages and disadvantages. The main disadvantage of the test from the back of the nose is that it can be uncomfortable.

For more about the viral test and how it works[1]

For more about the accuracy of the viral test [2]

Saying this, there are other testing methods that may become available in future, like saliva and antibody tests.

Saliva testing is not ready for public use yet

Testing for COVID-19 from saliva samples has also been used and has generated a lot of discussion internationally. This type of test not presently available in New Zealand, but there is work underway investigating where use of it might be safe and appropriate.

It's not available because scientists are still finding out whether saliva tests are as accurate as swabs from the back of the nose or throat, through looking at limitations at the sample collection and sample processing stages. To keep COVID-19 out of New Zealand we need to use the most accurate

[1] https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-health-advice-public/assessment-and-testing-covid-19/how-covid-19-testing-works
[2] https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-health-advice-public/assessment-and-testing-covid-19/covid-19-test-results-and-their-accuracy

test possible. The accuracy of saliva testing is estimated by testing the same person at the same time using two different methods (these are called paired tests), and comparing the results to make sure they are consistent. At this stage, saliva testing appears to deliver slightly less accurate results than the current methods used in New Zealand. Once there are conclusive results, scientists involved will publish their findings. But after this there is still time and effort needed to develop the findings into a process that works for the people being tested, the people collecting samples, and those who process them in laboratories.

And there are a few issues to iron out. Producing a saliva sample is not as easy as it sounds, and there is variability in the quality of samples taken. Saliva is also more difficult to process in a laboratory compared to a swab because it has air bubbles in it, and some people's saliva is much thicker than others. This can delay processing time and mean that repeat samples are sometimes needed. You can't eat or smoke before a saliva test is taken, because it may affect the accuracy of the test.

Saliva testing is likely to become available in New Zealand in the near future for some people that nasopharyngeal or oropharyngeal swabbing isn't right for, but the test isn't ready yet. It is not likely that saliva testing will replace the current methods entirely.

Antibody testing (serology) can show who has had COVID-19

When a person is sick, their body's immune system, which protects them against infections, produces antibodies to fight the disease so that the person recovers. Antibodies are commonly produced in the blood but may also be present in the lungs or nose.

Antibody testing (or serology) involves collecting blood samples and testing them for antibodies. This type of testing shows whether a person has had COVID-19 either in the past or is currently infected, but cannot determine if they are currently infected (and infectious to others).

Serology testing is available in some places for particular purposes, for example for understanding whether a persistent cough might be related to a past infection.

Antibodies usually protect a person from getting sick from the same virus again. This is called immunity. However, the protection does not always last for a long time. There have been a few reported cases worldwide of people getting COVID-19 twice within six months, but we don't know yet how common a second infection is. If immunity lasts for a long time then there is a better chance of vaccines protecting a person from infection for a long time.

If the number of people who have had COVID-19 within or returning to New Zealand starts to increase, it may become useful to identify people who already had the disease because this might help identify who is at risk from catching COVID-19.

For more about antibodies and COVID-19[3]

[3] https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-health-advice-public/about-covid-19/covid-19-what-we-know-about-infection-and-immunity