# Memorandum

## COVID-19 Testing Modalities

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| **To:** | Dawn Kelly, Private Secretary, Office of Hon Chris Hipkins | | |
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## Contact for telephone discussion

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## Action for Private Secretaries

N/A

**Date dispatched to MO:**

# COVID-19 Testing Modalities

## Purpose

1. This memo provides an overview of the suite of COVID-19 testing available for testing individuals (see Appendix One). Not all of these are currently in use in New Zealand. Wastewater and environmental-based swabbing are outside the scope of this memo.

## Assessment of testing modalities

### Testing modalities already in use in New Zealand

2. Nucleic acid amplification testing (including RT-PCR and TMA) using nasopharyngeal swab samples remains the 'gold standard' for diagnostic purposes and remains the foundation test for our COVID-19 response. Use of oropharyngeal/anterior nasal swabs is a suitable alternative for border workers who are being regularly tested. Testing using neat saliva as the sample type is available as a screening tests for border workers in quarantine and dual use facilities. The appropriate use of saliva as a sample type with RT-PCR and TMA tests within our context continues to be assessed.

3. Serological antibody tests form the basis of our investigative testing to assist in assessing historical infections. Serology is not a confirmatory diagnostic test for COVID-19.

4. Whole genome sequencing remains the basis for identifying strains and any new emerging variants as well as supporting investigation of chains of transmission.

### Consideration of additional testing modalities

5. Any additional tests that are added to our testing suite need to provide something over and above what we currently have. For example, advantages in cost, availability, sensitivity, speed of result and/or ease of sample collection.

6. The biggest drivers for implementing additional testing modalities at this time are to make tests available that can be done at an increased frequency in areas considered of higher risk, using a sample collection method that is well tolerated.

7. Additional testing needs to consider the impact on overall resources from sample collection to laboratory testing (including consumables and workforce considerations), as well as impact on the person having the sample taken.

8. Taking the above into consideration, LAMP tests and antigen tests continue to be assessed to inform future use but at this stage do not provide additional value over and above the current testing regime. Either may have potential in the future, if for example, we needed to expand our existing capacity in a situation of higher prevalence of COVID-19 in the community:

    a. LAMP is very fast and highly scalable with or without an extraction step. Sensitivity is, however, lower than for RT-PCR, meaning positive cases may be missed.

b. 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. Tests with acceptable performance may have potential for future use in particular circumstances, such as in remote communities where the turnaround time for PCR results may be extended.

## Next steps

9. COVID-19 testing technologies continue to evolve and we continue to monitor global trends and newly available data to adjust our testing settings as appropriate.

10. Additional information on testing modalities can be provided on request. We will continue to provide updates on alternative testing modalities as evidence emerges.

Sue Gordon
Deputy Chief Executive
**COVID-19 Health System Response**
Date: 4/3/21

## Appendix One: Testing modalities and sampling methods

| Test Modality | Available in NZ? | Sample type | Principle | Point of care (POC) | Comments |
|---|---|---|---|---|---|
| RT-PCR (Reverse Transcription polymerase chain reaction) | Yes | Respiratory samples[1] | Qualitative detection of SARS-CoV-2 nucleic acid. | Yes, some systems e.g. GeneXpert (a 45 min test time) could be adapted to POC | • High sensitivity and specificity<br>• Well validated tests<br>• Compatibility with many diagnostic laboratories<br>• Turnaround time (TAT) ~ 6 hours |
| TMA (Transcription mediated amplification) | Yes | Respiratory samples[1] | Qualitative detection of SARS-CoV-2 nucleic acid. | No | • High sensitivity and specificity<br>• Proprietary to Panther Hologic<br>• TAT ~ 6 hours |
| Antibody | Yes[2] | Blood | Detects SARS-CoV-2 antibodies in blood. Will detect people that have been exposed to COVID-19 or that are vaccinated. | Yes – can be conducted in a laboratory or POC | • Not suitable for surveillance<br>• Identifies patients previously exposed to COVID-19; and/or current or recent infection.<br>• Total antibody or IgG have greater accuracy.<br>• IgA and IgM lack sensitivity.<br>• Limited clinical utility for diagnosis in an acute setting other than identifying historical cases.<br>• Testing three to four weeks after onset of symptoms optimises accuracy.<br>• Antibody testing will become more commonplace in the post-vaccine era as people seek to determine if they have protective antibodies. |
| Whole Genome Sequencing (WGS) | Yes | SARS-CoV-2 positive respiratory samples | Sequencing of 30,000 RNA nucleotides that comprise the SARS-CoV-2 genome | No | • WGS can be used to compare SARS-CoV-2 genomes from multiple cases to investigate community transmission by identifying source of infection and routes of transmission.<br>• WGS can be used to monitor emerging variants. |
| RT-LAMP (Loop-mediated isothermal amplification) | No, some research ongoing in NZ | Respiratory samples[1] | Qualitative detection of SARS-CoV-2 nucleic acid. | Yes<br>e.g. ID Now<br>~ 15 minutes | • Technique that amplifies viral nucleic acid; Test can be conducted at room temperature, done in a single tube, and colour-marked so that the mixture changes colour if target RNA is present. Does not require sample purification or a thermal cycler.<br>• Typically of lower sensitivity than RT-PCR. |
| Antigen | No[3] | Respiratory samples[1] | Detects SARS-CoV-2 viral proteins (antigens). | Yes | • The antigen(s) detected are expressed only when the virus is actively replicating; therefore, such tests are best used to identify acute infections, not early infection as targeted in NZ.<br>• Rapid antigen POC tests may also be useful in large outbreak settings and for repeated screening of individuals in high-risk settings.<br>• Small number of kits currently undergoing a validation process at ESR. |

[1]Respiratory samples include: Nasopharyngeal, Oropharyngeal &/or Nasal (anterior nares), Saliva (neat or swab)*. * *Saliva currently undergoing validation.*
[2]Used for Pre departure testing and confirmation of historical exposure
[3]Medsafe Section 37 prohibits importation and use of point of care antigen kits.