Public Health Laboratory Network – Communicable Diseases Network Australia

Joint statement on patient referral and respiratory virus test requesting for winter 2022

Revision history

Version	Date endorsed	Revision notes
1.0	28 June 2022	Initial document

On 31 March 2022, the Australian Health Protection Principal Committee released a statement on winter preparation. This statement notes that as Australia enters the final phase (Phase D) of the National Plan and is living with COVID-19, the 2022 winter may present challenges to health systems, healthcare providers, aged care and disability care residents, communities and to the economy arising from the likely cocirculation of SARS-CoV-2 (the virus that causes COVID-19) and other co-circulating respiratory viruses.

Symptomatic people otherwise not at risk of severe illness are expected to:

- to stay at home, and
- avoid other people until symptoms resolve, and
- follow their jurisdiction's public health requirements.

In Australia, nucleic acid amplification (NAA) testing (such as polymerase chain reaction (PCR) testing) on a throat and bilateral deep nasal (or nasopharyngeal) swab is the benchmark for confirmation of an acute respiratory virus infection. During winter, with many circulating viral respiratory pathogens, a multiple pathogen testing approach using NAA may be implemented. In this situation, the same throat and bilateral deep nasal (or nasopharyngeal) swab can be used to test a specimen against a selection of viral and/or pathogen targets simultaneously (for example, SARS-CoV-2, *Influenza A* virus, *Influenza B* virus, and *Respiratory Syncytial* virus (RSV)[1], at the same time). This may be referred to as a respiratory virus panel.

Using a multiplex in vitro diagnostic (IVD) device is at the discretion of microbiology laboratory management, noting other equivalent approaches may be more appropriate. State and territory private and public testing arrangements should support the targeted testing of multiple respiratory pathogens simultaneously (for

[1]In addition to COVID-19, and Influenza (laboratory-confirmed), Respiratory Syncytial Virus (RSV) infection is a nationally notifiable disease within Australia. RSV infection can be severe in young children. National data helps inform research into treatments and vaccines.

example, multiplex[2] NAA), where clinically indicated. The prevalence of influenza in the community will inform decisions on the appropriate timeframe for this to commence.

This document provides guidance for pathology providers and for medical and nurse practitioners who are referring patients with respiratory symptoms for testing following a clinical assessment. This document does not relate to people self-presenting for testing at respiratory centres and testing hubs, or self-testing.

For medical and nurse practitioners:

- Consider requesting multiple respiratory virus testing for individuals with acute respiratory infection symptoms at risk of severe disease (for example, residents of aged care facilities or immunocompromised individuals), where:
    - clinically indicated, i.e., where laboratory-based confirmation of the type of respiratory infection will affect the clinical care that the individual receives, or
    - those that live or work closely with individual/s at risk of severe disease.
- The accurate completion of pathology referral forms is critical. Ensure referral forms include at a minimum SARS-CoV-2, *Influenza A* virus, *Influenza B* virus and where indicated, RSV[3] for these individuals. If unsure, please include 'respiratory virus panel' on the pathology referral form[4]. Other respiratory viruses cocirculating in the community should be considered for inclusion, where known and where testing capacity allows. This will help to conserve resources and ensure optimal surveillance is achieved.
- Supply relevant clinical information and patient history to assist the pathology provider. For example, please provide details (where relevant) of:
    - The patient's clinical symptoms.
    - Comorbidities and immunosuppressive medications that contribute to a higher risk of severe respiratory illness.
    - International travel within the previous 14 days.
    - Whether the individual works, lives with, or provides care for individual/s at risk of severe disease.
- Medical and nurse practitioners should also consider jurisdictional public health guidance for testing in high-risk settings in outbreak situations.
- Any negative result must also be considered in the context of the clinical presentation of the individual, and if a viral respiratory pathogen is suspected, this should be followed-up with another test after 24 hours.
- Repeat testing should be based on the CDNA COVID-19 national guidelines for public health units.

For pathology providers:

- Australian pathology laboratories use different testing approaches according to their local epidemiological

[2] The term multiplex denotes a technical methodology. This statement is not intended to dictate the technical approach. The aim is to ensure appropriate viral pathogens are considered in the testing matrix. Because of the availability of notification requirements and available treatments, the main targets are SARS-COV-2, Influenza A virus, Influenza B virus, and RSV.

[3] Depending on the platforms and IVDs used by the pathology provider, other targets may be tested and reported.

[4] If bacterial respiratory pathogens are suspected (for example, Bordetella pertussis), please request this testing on the pathology form.

context, capacity, and established workflows. Therefore, if not requested by the referring practitioner, multiple pathogen testing workflows for respiratory viruses may be determined by the receiving pathologist.

- The development and distribution of a communication plan is recommended to assist referring medical practitioners when making decisions about referral of patients for laboratory-based respiratory virus testing, and for testing to be once more embedded in a patient-centred clinical management paradigm.

Rapid antigen detection testing

Rapid antigen tests (RATs) are intended for use at the point-of-care (PoC), or near person testing, to detect the presence of viral protein from SARS-CoV-2. These tests can provide results within 15–30 minutes. Most current RATs claim that maximal sensitivity is achieved when testing symptomatic individuals within the first 5–7 days of the onset of symptoms. While less sensitive than NAA tests, in times of high prevalence of COVID-19 and where laboratory testing is overwhelmed, rapid antigen detection can be used as an alternative diagnostic approach for those with COVID-19 symptoms to conserve laboratory testing capacity. Such situations require communication with relevant practitioners and public health authorities for changes to be made. Currently, rapid antigen detection devices that are able to detect more than one respiratory pathogen are not recommended, given the history of poor performance for the detection of *Influenza A* virus antigen in the past. For more information, please see the PHLN and CDNA joint statement on SARS-CoV-2 rapid antigen tests, located on the Department of Health website.

Regulatory approval of multiplex in vitro diagnostic (IVD) devices for supply in Australia

Any testing technology new to Australia requires very careful assessment by the Therapeutic Goods Administration (TGA) before legal supply in Australia is approved.

As of 10 June 2022, the TGA has approved eight multiplex NAA assays that detect *Influenza A* virus, *Influenza B* virus and SARS-CoV-2 with or without other respiratory viruses, including RSV. Six of the assays are intended for laboratory use, and two are intended for use at the point-of-care by a health care professional. No multi-target RATs (also referred to as Combination RATs) have been approved as of 10 June 2022. However, an up to date list of approved tests for COVID-19 (including multiplex NAA assays that include a combination of both viral *and* bacterial respiratory pathogen targets and any multi-target RATs in the future) is maintained on the TGA website (https://www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-australia).

It is recognised that laboratory-based multiplex testing is likely to be in high demand throughout the coming winter. All applications for multiplex assays which include SARS-CoV-2 in combination with *Influenza A* virus, *Influenza B* virus, and RSV targets, and particularly those that require high-throughput instrument platforms are being prioritised by the TGA.

Medical benefits schedule (MBS) SARS-CoV-2 testing reimbursement

Existing arrangements for SARS-CoV-2 testing under MBS items 69479 and 69480 have been extended to 30 September 2022.

Current MBS pathology arrangements support concurrent testing for COVID-19 and other respiratory infections. Pathology providers are able to co-claim MBS item 69479 or 69480 with a MBS microbiology item should additional infectious respiratory targets be requested by a medical practitioner for the clinical management of their patient (for example MBS item 69496, for three or more additional infections respiratory targets).

For more information, please refer to Extension of the SARS-CoV-2 (COVID-19) Pathology Items.

Whole genome sequencing

For SARS-CoV-2

Whole genome sequencing (WGS) is used to assign lineages of SARS-CoV-2 isolated from patient samples. WGS has an important role in understanding genomic diversity, detection of emerging variants of concern, detection of new mutations and monitoring transmission. Unlike early in the COVID-19 pandemic where low positivity rates were observed, it is no longer possible to sequence every positive case in a high caseload environment to confirm the viral lineage in a specimen. Therefore, a targeted WGS strategy is being implemented as outlined in the Communicable Diseases Genomics Network (CDGN) Sampling Strategy for SARS-CoV-2 Genomic Surveillance.

The Strategy outlines suggested priority groups for targeted sampling, this includes, but is not limited to, patients admitted to hospital and/or critical care wards, to identify whether any SARS-CoV-2 viral lineages are associated with increased disease severity.

In the current context where hospitalisation numbers are lower, there is a need to re-evaluate sequencing strategies across Australia with a focus on winter preparedness and to ensure comprehensive and representative sequencing information is available to inform public health response decisions. This revision is being led by the CDGN, which is an Expert Reference Panel of the Public Health Laboratory Network (PHLN).

For Influenza virus

As per usual best practice for seasonal influenza surveillance, pathologists are encouraged to refer a representative selection of positive influenza samples to their public health reference laboratory for further characterisation and/or further referral to the World Health Organization Collaborating Centre for Reference and Research on Influenza, where appropriate. Representative sampling (from non-PHLN labs) would ideally be 5–10 samples per week during the season and 2–5 per fortnight outside of the season.