Serology testing capabilities in NSWHP

Position on testing of individuals for travel or other non-medical purposes

Background

On 2 November 2020, the Chinese Government issued a requirement for anyone wanting to enter China to provide evidence of their recent negative COVID-19 test results (both NAT on a respiratory tract sample and IgM from a serum sample) 48 hours ahead of travel.

The Chinese Consulate subsequently contacted NSW Health to informing them of this requirement, which will become effective from 8 November 2020.

NSW Health has issued guidance in response to this, directing that individuals requiring testing for travel purposes should be referred to private pathology providers.

NSWHP understands that private pathology providers might not currently have the capabilities to undertake IgM serology testing in-house. NSWHP has had no direct communication with private providers in relation to this specific matter.

Current capabilities for IgM antibody testing in NSW

NSW Health Pathology currently has one validated assay, the immunofluorescence assay (IFA) that can detect the three antibody markers (immunoglobulin G (IgG), immunoglobulin A (IgA), and immunoglobulin M (IgM) found in COVID-19 (SARS-CoV-2).

This IFA was developed by Dr Linda Hueston, Principal Hospital Scientist and Chief Serologist at NSWHP’s ICMPR Westmead Laboratory using virus culture material and in the absence of any commercially available tests.

This serology test detects antibodies that the human body creates to fight SARS-CoV, the virus that causes COVID-19, and indicates recent or past infection.

In addition to ICMPR-Westmead, COVID-19 IgG serology testing is currently available via NSW Health Pathology’s laboratories at John Hunter Hospital, Royal North Shore, Royal Prince Alfred, Concord, Randwick and Liverpool. IgM serology is currently only available at NSWHP’s ICMPR Westmead.

NSWHP has been awaiting the arrival of commercial IgM test kits in Australia for some time so they might investigate their usage for testing within the community.

Current applications of serology testing for the NSW community

Testing is currently prioritised to support management of the public health response to the COVID-19 pandemic. This is due to current laboratory testing capacity, the manual nature of IFA testing, and direction of the NSW Health Protection Unit. It is used for confirmatory testing and contract tracing purposes in managing clusters and outbreaks.

Serological testing has many uses, such as determining the extent of infection in a population; estimating the date of exposure and infectious period in confirmed cases; making a retrospective diagnosis in individuals who have recovered from infection prior to testing; and guiding the public health response to an outbreak.

Further expansion of serology testing capabilities

NSWHP is in the process of expanding its capabilities and capacity for COVID-19 serology testing, which will include IgM.
Abbott, Roche and other companies have indicated eventual availability of high-throughput commercial assays for COVID-19 IgM serology testing.

NSWHP is in liaison with these vendors to explore supply chain assurance and the feasibility of carrying out essential assay validation studies. This is an essential step to determine efficacy and reliability.

Scientific validation work will be coordinated across the NSWHP Microbiology and Clinical Chemistry Clinical Streams by NSWHP’s Dr Catherine Pitman, Clinical Microbiologist and Public Health Pathology Specialist.

Recommendations for future clinical application of any new COVID-19 commercial assays and reagents require final approval by NSWHP’s Incident Management Team.

Assuming successful validation and supply chain assurances, NSWHP aims to establish high-throughput serological COVID-19 testing for travel and other non-medical purposes in due course.

Key considerations and challenges

- Testing of asymptomatic people for COVID-19 who require clearance for travel purposes, work, study or other reasons is not part of routine public health testing and is not covered by Medicare.
- NSWHP will require a fee for service for COVID-19 testing for purposes other than diagnosing active or suspected infection regardless of whether NAT and/or serology testing is requested. This fee would need to include issuance of a written record of the result.
- NSWHP does not have capacity to provide serology testing on behalf of private pathology providers at this stage.
- NAT testing for COVID-19 requires a nasopharyngeal swab while serology testing for antibodies requires a blood sample. These two samples may not be collected currently at the same sites/clinics.
- Collection of blood tests for serology testing of asymptomatic people for travel purposes would require additional logistical arrangements for referral pathways, transport needs, etc.
- NSWHP is exploring models for provision of combined collection services.
- There are assay limitations caused by false positive / false negative results linked to varying NAT and IgM results that require understanding of their potential clinical significance.

Next steps

- NSWHP will advise all stakeholders (staff, Ministry, LHDs, etc) of its ongoing commitment to providing expert serology testing as part of the state’s public health response. At this stage, this does not include testing of asymptomatic people requiring results for travel or other non-clinical purposes.
- NSWHP will also advise stakeholders of its plans to expand serology testing for asymptomatic people for travel and other purposes and does not provide serology testing for private pathology providers.
- NSWHP will work with commercial vendors to carry out verification of newly available commercial assays for high-throughput COVID-19 serology testing led by NSWHP’s Microbiology and Clinical Chemistry Clinical Streams with support by Dr Cath Pitman.
- Enquiries to laboratories by commercial vendors will be directed to Mr Simon Holmes.
- NSWHP is examining new service models to ensure safety, reliability and timeliness of sample collection, transportation, testing and reporting for asymptomatic people.
- NSWHP is finalising plans for the expansion of its newly dedicated COVID-19 call centre to enable statewide inbound calls. This would help support the growing demand for COVID-19 testing and result notification for travel and other purposes.
- NSWHP is also developing the capabilities and framework to provide patients with a written record of COVID-19 results beyond its SMS service, and in line with legal and privacy requirements.
- NSWHP will work to build a range of supporting capabilities, including transportation, LIMs reporting, billing, etc to support testing of asymptomatic people.