

Rapid antibody COVID-19 test kits



Health
Pathology

NSW Health Pathology's position statement

NSWHP recognises the high level of interest in point of care or rapid testing for COVID-19 in the light of emerging technologies and the desire to provide a timely response to the current global public health pandemic.

After careful consideration, NSWHP holds concerns about the quality and clinical utility of the rapid antibody tests being offered to NSW Health by a broad range of vendors. These concerns encompass their use as an alternative to existing Real Time PCR testing for the detection of the virus that causes COVID-19; and/or their use to access self-testing to quickly assess whether or not a person is infectious.

NSW Health Pathology (NSWHP) endorses the Public Health Laboratory Network's (PHLN) statement issued on 20 March 2020 on Point of Care Serology Testing for SARS-CoV-2 (the virus that causes COVID-19).

Rapid antibody test kits for COVID-19 have very limited utility in diagnosis of an active case. They cannot show if someone is currently infected and at increased risk of becoming seriously ill or spreading the infection to others. Their utility in testing healthcare workers and high-risk groups in the current testing criteria is not yet established and advice from the Public Health Laboratory Network would counsel against widespread adoption.

Due to the high number of rapid COVID-19 test kits being proffered to NSW Health, and the recent announcement that a number of these have been approved by the Australian Government's Therapeutic Goods Administration (TGA), NSWHP has begun evaluating a sample of these devices. It is our understanding that the TGA has begun assembling material from vendors offering these rapid test kits, so that formal evaluation of their claims may be assessed, and the performance of the test kits validated.

NSWHP has completed its first evaluation of one of these rapid antibody testing kits. We believe that this may be the first evaluation of such tests kits completed in Australia.

In summary, this evaluation of one test system concluded that the specific rapid antibody test kit could not be recommended for use in the diagnosis of acute infection, as a means of determining immunity in an individual, nor as a seroprevalence tool.

There were several reasons for this conclusion, principally however the test kit was found to have an unacceptably low sensitivity for both IgG and IgM antibodies. This would result in 35% of patients being misclassified as past infection, when they were current.

This would mean 35 out of every 100 patients tested could be given clearance to go back to work or cease self-isolation when they remained infectious. Evidence also existed that the strength of antibodies deteriorated through the testing process, making sensitivity an important factor in producing accurate results. Antibodies do

not necessarily equate to long-term or perpetual immunity. It will be some time before it can be established whether we can be truly protected from COVID-19 through immunity or vaccination.

Serology tests can be used to help understand the distribution of the disease across our community. NSWHP supports comprehensive serology surveys. However, it does not recommend using rapid antibody test kits for this purpose. Existing IFA (Immunofluorescence Assay) testing is significantly more accurate and practical for the number of samples requiring testing in this type of public health analysis.

NSWHP is in a position to participate in prevalence studies within the community as well as proceeding with serology tests on serum already held in our specialist labs and approved for use in this type of public health analysis. As outlined in the PHLN statement, it is recommended that mass surveys of immunity to retrospectively determine the true prevalence of infection should be done with enzyme immunoassays and not lateral flow devices such as the rapid testing kits.

Identifying those with active infection using existing diagnostic testing is the greatest priority at this time – to manage their care and prevent the spread of infection. Rapid testing kits do have some utility however in some situations. These would include in situations where the numbers of potential infections are overwhelming, such as in the United States, the United Kingdom, and parts of Europe. In such situations, high volume, fast-turnaround tests would prove better than no testing at all. It remains however that many people will be misdiagnosed.

Rapid testing kits could potentially be used where there is a proven outbreak of COVID-19 in an institution such as a prison or aged care facility, where rapid understanding of the extent of the outbreak was needed and quarantining was already established. Again, testing in such situations would give only an indication of the infection rather than confirmation. It would require significant repeat testing in individuals and such institutions would need to effectively manage a 'quarantine' operation.

At this time, NSWHP would not recommend a bulk purchase of COVID-19 rapid antibody test kits. These do not have a significant role to play in the statewide public health response to COVID-19, now or in the foreseeable future.

NSWHP anticipates the market for these rapid testing kits is more likely to fall in the primary health care sector, or with individuals in the community. It is believed that the Commonwealth Department of Health has purchased over one million rapid testing kits; however, it remains unclear how these will be distributed or utilised.

NSWHP has committed to evaluating several other such rapid lateral flow kits to ensure comprehensive and clear advice about this methodology is provided.