syzygy
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Sullivan Nicolaides PATHOLOGY
Quality is in our DNA

Clinical utility of SARS-CoV-2 antibody testing

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Sullivan Nicolaides Pathology has recently introduced COVID-19 antibody testing. The addition of the SARS-CoV-2 IgG test will provide additional epidemiological information and assist in understanding the extent of past sub-clinical infections where PCR testing was either not performed or falsely negative.

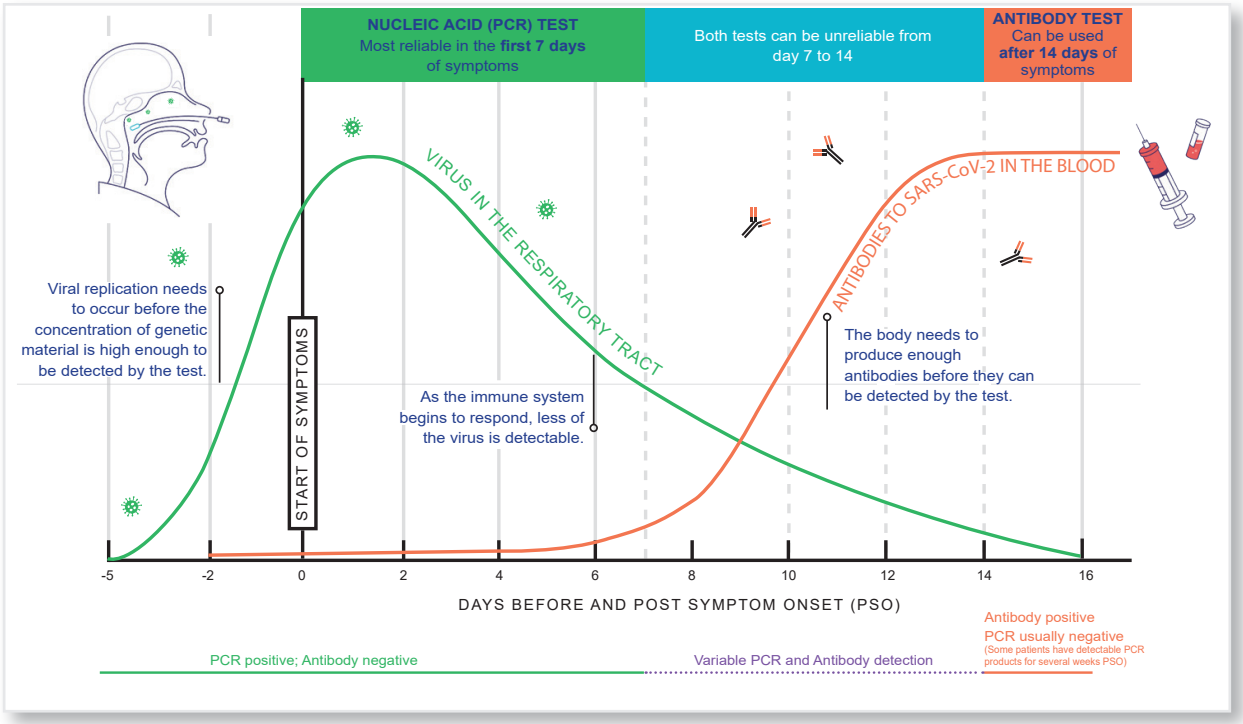


Figure 1: Diagnosis of SARS-CoV-2 infection

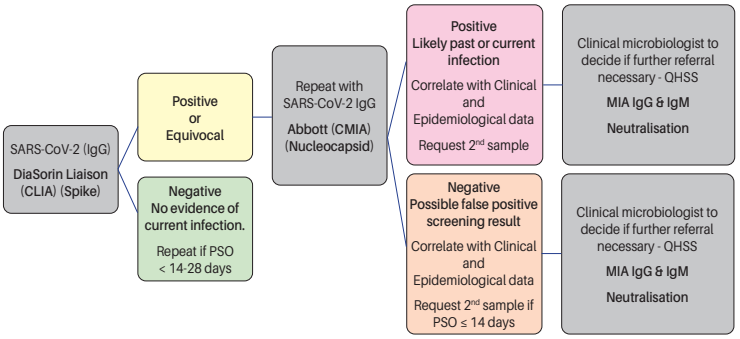
Key points

- A respiratory collection must be tested using reverse transcriptase polymerase chain reaction (RT-PCR) when acute infection is suspected.
- SARS-CoV-2 serology is NOT useful for the acute diagnosis of COVID-19.
- An acute serum may be useful to demonstrate specific SARS-CoV-2 IgG seroconversion at a later date.
- The IgG antibody response may take 2-4 weeks following infection to develop.
- IgM or IgA antibodies add little value in the diagnosis of COVID-19.
- SNP is only reporting on the detection of specific SARS-CoV-2 IgG antibodies.
- Some infected individuals (~5%) may not develop an immune response.
- Antibody levels may wane over time and become non-detectable – this is being closely followed.
- Whilst there is likely to be a reasonable correlation with protective neutralising antibodies this has not been proven.
- Even if protection is conferred, its durability is unknown.
- Serology for SARS-CoV-2 is available on request.

Testing for SARS-CoV-2 IgG

The prevalence of SARS-CoV-2 IgG in the Australian population is currently likely to be low (<0.1%). This means the overall Positive Predictive Value (PPV) is low and in the order of 10%. To improve PPV of a positive result, two independent tests targeting different antigenic sites of the virus are used (Figure 2).

The initial test is the DiaSorin Liaison chemiluminescence immunoassay (CLIA) that has recombinant Spike S1 & S2 as its target. If the result returns as equivocal or positive, the sample is retested on the Abbott chemiluminescence microparticle assay (CMIA) that targets the nucleocapsid of the virus (N) (Figure 3 see over).



PSO: post symptom onset
MIA: microsphere immunoassay
QHSS: Queensland Health Forensic & Scientific Services

Figure 2: Algorithm in use at Sullivan Nicolaides Pathology for COVID-19 serology

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Our new website guide makes Ambulatory Blood Pressure Monitoring easy for your patients

We have added a new step-by-step online guide to the Sullivan Nicolaides Pathology website to help your patients navigate their way through Ambulatory Blood Pressure Monitoring (ABPM).

Using graphics and a user-friendly scrolling pathway that can be used on a desktop, tablet or mobile platform, we demystify the process and show them what to expect when you refer them to us for monitoring.

We take them through booking an appointment, finding a collection centre, preparing for their fitting, paying, having a monitor fitted, and what to expect when wearing it. We also provide a comprehensive FAQ on common concerns and how to seek help.

Having blood pressured monitored can be daunting. By improving your patient's experience and providing them with support in this way, our aim is to help them stay positive.

We'd be delighted if you have the time to explore this new website guide. Tell us what you think. Share it with your patients and colleagues. In this way we can keep improving the services we offer.

The ABPM information can be found at http://www.snp.com.au/our-services/cardiology/ABPM.

Having your monitor fitted

Testing for SARS-CoV-2 (continued)

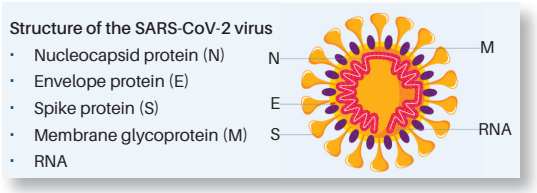

Figure 3: Structure of the SARS-CoV-2 virus

When both tests are positive, the PPV increases to above 80%. Where the reflex test is negative, it is more likely that the true result is negative; however, clinical and epidemiological information should always be taken into account, and repeating the test in 2-4 weeks may be indicated. Consultation with a clinical microbiologist is recommended and referral to a reference laboratory for additional testing may be suggested. Providing clinical details on the request form, such as date of onset of symptoms, and risk factors such as travel, or known positive COVID-19 patient, or close contact with a known case, will assist with interpretation of serological results.

Possible reasons for recommending use of SARS-CoV-2 serology

These include:

- Testing patients who have had symptoms consistent with COVID-19 but are PCR negative, or were not tested, or have unexpected positive or inconclusive PCR results.
- Seroepidemiological studies to define the degree of population infection.
- Surveillance of frontline healthcare workers to define potential occupational infection.
- Convalescent patients for plasma donation.
- Patients who may have been, or are, part of an outbreak investigation to facilitate contact tracing.
- Estimating timing of infection to help define the likely infectious period where this is not evident from clinical symptoms or exposure history.
- Evaluation of the immune response to candidate vaccines.

A word on Point-of-Care lateral flow IgG and IgM tests

- A number of these point-of-care tests (POCT) were included in the Australian Register of Therapeutic Goods early in the pandemic under an Emergency Use Authorisation clause.
- They are authorised for use only under medical supervision.
- Post market review commissioned by the Therapeutics Goods Administration of Australia suggests they have limited, if any, role in the diagnosis or clinical management of individual patients.
- The role of POCT in population-level serosurveys remains to be seen.
- Overall, the findings remain in keeping with the position statements by the Public Health Laboratory Network and the Royal College of Pathologists Australasia.

References

Public Health Laboratory Network (PHLN) guidance for serological testing in COVID-19. https://www.health.gov.au/resources/publications/phln-guidance-for-serological-testing-in-covid-19

Public Health Laboratory Network Statement on point-of-care serology testing for SARS-CoV-2 (the virus that causes COVID-19). https://www.health.gov.au/resources/publications/phln-statement-on-point-of-care-serology-testing-for-sars-cov-2-the-virus-that-causes-covid-19

RCPA Position Statement Subject: COVID19 IgG/IgM rapid POCT tests https://www.rcpa.edu.au/getattachment/bf9c7996-6467-44e6-81f2-e2e0cd71a4c7/COVID19-IgG-IgM-RAPID-POCT-TESTS.aspx

Post market review of COVID-19 point-of-care tests https://www.tga.gov.au/post-market-review-covid-19-point-care-tests

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