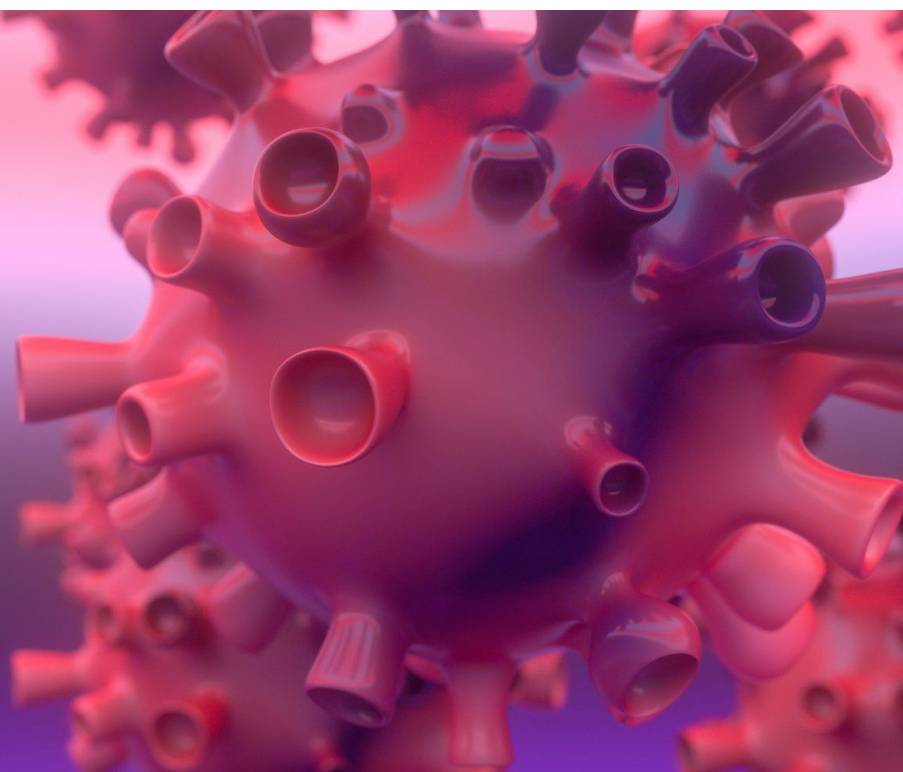


AMPATHCHAT

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COVID-19 antibody testing

Do you suspect
that your patient
previously had
COVID-19?



Ampath would like to inform you of the availability of a new SARS-CoV-2 antibody test. This test may be used to determine whether a patient has previously been exposed to SARS-CoV-2, the virus causing COVID-19.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever, flu-like symptoms or symptoms of acute respiratory illness (e.g. a cough or difficulty breathing). However, some patients may only have had mild symptoms or may have been asymptomatic. Based on what is known about the SARS-CoV-2 virus that causes COVID-19, signs and symptoms may appear any time from two to 14 days after exposure to the virus, with the median incubation period being approximately five days.

What do we know about the antibody response to SARS-CoV-2?

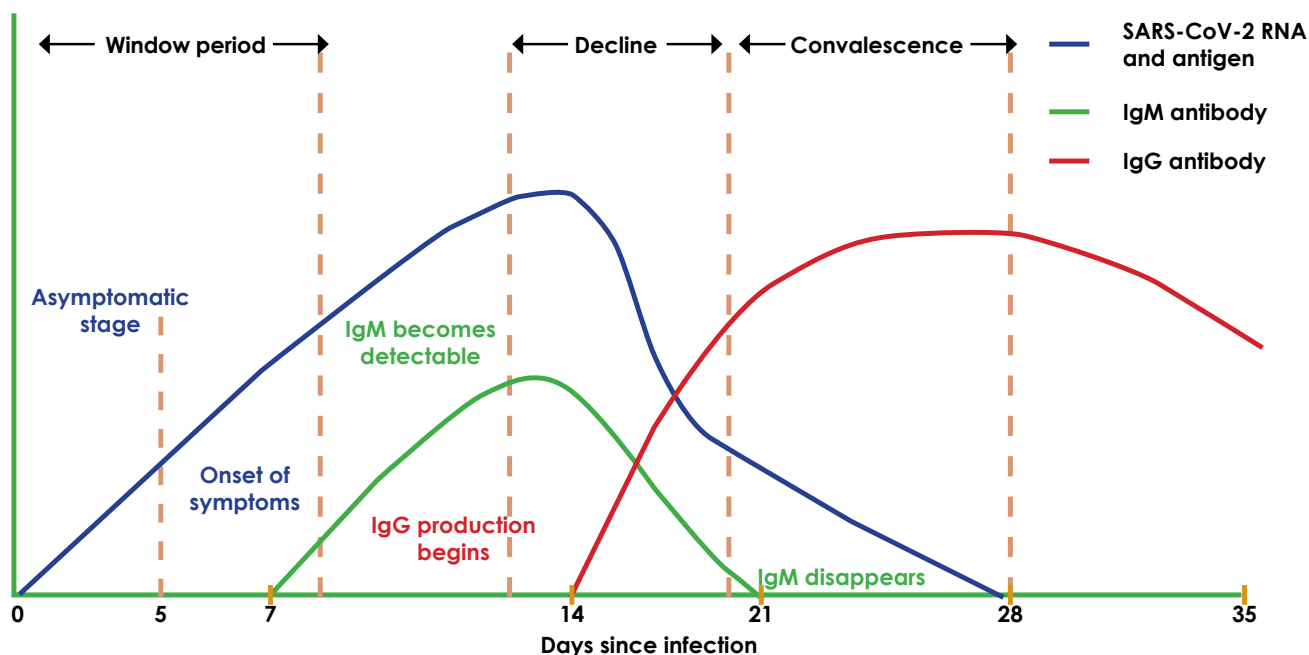
The SARS-CoV-2 is a novel virus that has only been studied since December 2019. Therefore, there is a paucity of information on the immune response to this virus, as well as long-term and protective immunity. We do know that the antibody response to SARS-CoV-2 seems to follow a

typical pattern seen in most viral infections. After infection, patients enter into an incubation period before becoming symptomatic or shedding virus. During this time, the immune system encounters the virus and starts mounting an antibody response. Initially, no circulating antibodies would be present. This is called the diagnostic window period.

The first antibody class to develop is usually IgM, followed by IgG a few days later. It is estimated that IgM or IgG is detectable in 90% of infected individuals by Day 14 to Day 16 after the onset of symptoms. The graph overleaf helps to explain the diagnostic window period and the development of antibodies to SARS-CoV-2.

What are the current indications for SARS-CoV-2 antibody tests??

- Epidemiological research or community surveillance in the public or private sector, especially in the following settings:
 - Healthcare setting
 - Care homes
 - Institutions
 - Workplace
- Outbreak investigation and prevention
- Limited clinical use more than 14 days after symptom onset



for the following clinical scenarios:

- To diagnose COVID-19 in patients who are admitted with suspected SARS-CoV2 infection, but who test negative for RT-PCR as an ancillary investigation. This will include children with suspected paediatric inflammatory multisystem inflammatory syndrome (PIMS), who may test negative by RT-PCR.
- To diagnose COVID-19 retrospectively in patients who have recovered from a COVID-19 compatible illness.

Who should NOT be tested?

Patients who are symptomatic or suspect that they may have a current COVID-19 infection. This test is not recommended to diagnose or rule out active COVID-19 infection.

Please note: Suspected current COVID-19 infection should be diagnosed by PCR on a respiratory swab or lower respiratory tract specimen.

What specimen should be used for SARS-CoV-2 antibody testing?

A single blood specimen is collected in a clotted tube (red or yellow top). There are no special specimen handling requirements and specimens can be collected at any routine Ampath lab or depot that does not reside within a hospital facility.

What does it mean if the specimen tests negative for SARS-CoV-2 antibodies?

A negative test result means that SARS-CoV-2 IgG antibodies could not be detected in the specimen. However, a negative result does not rule out previous exposure to COVID-19, as IgG antibodies to SARS-CoV-2 can only be detected reliably 14 days after symptom onset. The test result may therefore be negative if the specimen was collected too soon after infection. The rate at which antibodies develop and antibody levels are highly variable, depending on an individual patient's immune system. It may also be possible that some patients with SARS-CoV-2 infection may not develop antibodies at all, particularly in patients with mild or no symptoms. Recent literature has also indicated that antibodies may already start to wane by approximately three months after the infection.

What does it mean if the specimen tests positive for SARS-CoV-2 antibodies?

A positive test result means that it is very likely that the patient has or had COVID-19 and has developed an antibody response to the virus. Depending on the clinical history, an active COVID-19 infection should be ruled out by SARS-CoV-2 PCR testing, as patients with recent illness may sometimes still be infectious, despite starting to develop antibodies to SARS-CoV-2. There is also a very small chance that this test can give a false positive result, e.g. a cross-reaction with another viral antibody. From our own internal investigation and the literature, the estimated specificity of this test is approximately 99% or more. As SARS-CoV-2 is a new virus, we do not know for certain that the presence of IgG antibodies will be indicative of protective immunity or what the duration of immunity will be. Please note that laboratory test results should always be considered in the context of patient history, clinical observations and epidemiological data.

Should there be any doubt regarding the interpretation of this test result, please phone your local pathologist or the Immunology Department at the Ampath National Reference Laboratory on 012 678 0614/3 for advice.

Resources

1. Patel R, Babady E, Theel ES, Storch GA, Pinsky BA, St. George K, Smith TC, Bertuzzi S. 2020. Report of the American Society for Microbiology COVID-19 International Summit, 23 March 2020: Value of diagnostic testing for SARS-CoV-2/COVID-19 (mBio 11:e00722-20. <https://doi.org/10.1128/mBio.00722-20>).
2. To KK, Tsang OT, Leung WS, Tam AR, Wu TC, Lung DC et al. 2020. Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: An observational cohort study. *Lancet Infectious Diseases*, 23 March 2020 (pii: S1473-3099(20)30196-1).
3. Abbasi J. 2020. The promise and peril of antibody testing for COVID-19. *Journal of the American Medical Association*. Published online 17 April 2020. doi:10.1001/jama.2020.6170.
4. Gray CM, Peter J, Mendelson M, Madhi SA, Blackburn JM. 2020. COVID-19 antibody testing: From hype to immunological reality. *South African Medical Journal*. Published online 27 July 2020. doi.org/10.7196/SAMJ.2020.v110i9.15155