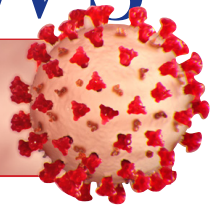


THE PATHCARE NEWS

THE ROLE OF ANTIBODY TESTING FOR SARS-COV-2



What types of COVID-19 tests are available?

| TYPE OF TEST | SPECIMEN |
|---|--|
| RT-PCR to detect viral RNA gene targets in clinical specimens | Respiratory swab or lower respiratory tract sample |
| Serology tests detect the host’s immune response to the virus | Serum or plasma |

Because the sensitivity of laboratory based serology tests and rapid point-of-care tests are too low within the first 14 days after SARS-CoV-2 infection (causing COVID-19), reverse transcriptase-polymerase chain reaction (RT-PCR) remains the current gold standard of diagnosis of an acute infection.

What is the estimated variation over time of diagnostic tests for the detection of SARS-CoV-2 infection?

Different diagnostic tests may be positive over different time points of the infection, as presented below.

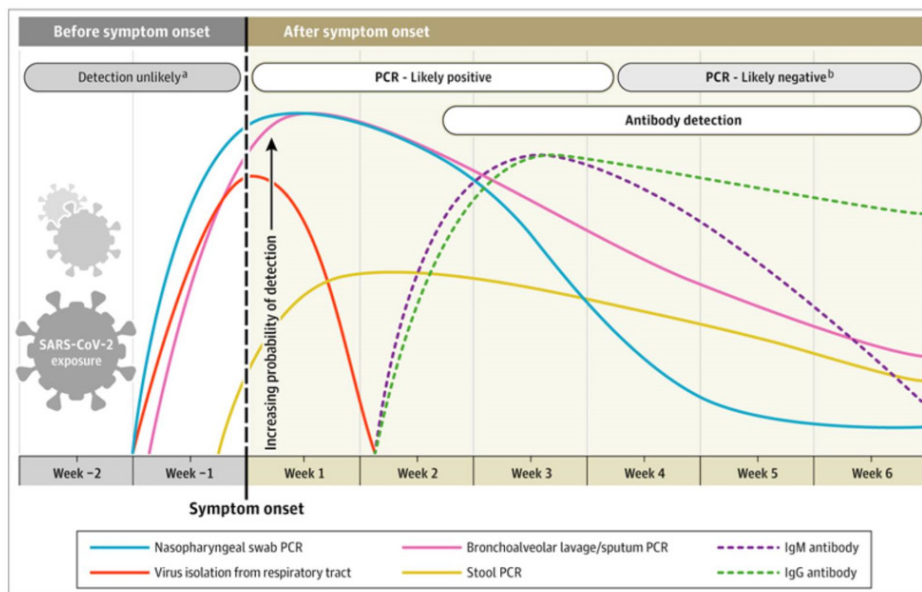


Figure 1: Estimated variation over time in diagnostic tests for detection of SARS-CoV-2 infection relative to symptom onset. (Downloaded from <https://jamanetwork.com> on 31 May 2020.)

ANTIBODY TESTING

How is antibody testing performed?

The patient’s serum or plasma is used to detect either the IgM, IgG, IgA or various combinations of these antibodies directed against SARS-CoV-2. Rapid tests (based on lateral flow principle) are available but have lower sensitivity than laboratory based (“formal”) antibody tests, and may also be less specific (see Department of Health recommendations below).

What does a positive antibody test represent?

- Prior exposure and possible immunity to SARS-CoV-2.

What are the reasons for a negative antibody test?

- No previous exposure to the virus
- Test done too early in course of the disease.
- The patient did not produce antibodies at all or may have had a past infection with loss of antibodies

The lag time ("window period") before the IgM and IgG antibodies appear is approximately 2 weeks, but may vary from patient to patient. Serology tests can therefore be expected to yield positive results from late in the course of acute illness (often >10 days after onset) or during convalescence. The level of production as well as the duration of antibodies may vary in different patients. Preliminary data indicates that antibody levels in some patients may revert to being undetectable beyond 21 days from symptom onset.

The role of antibodies in the diagnosis of COVID-19

The current guidelines issued by the Department of Health recommends that antibody testing can be used to:

- Diagnose COVID-19 retrospectively in patients who have recovered from a COVID-19 compatible illness and are negative by SARS-CoV-2 PCR.
- Diagnose COVID-19 in patients who are admitted with suspected SARS-CoV-2 infection but who test negative for RT-PCR as an ancillary investigation. This will include children with suspected multisystem inflammatory syndrome (MIS-C) who may test negative by SARS-CoV-2 PCR

It can also be used as part of epidemiologic investigations and research studies. Please see the Department of Health recommendations for a full description of use cases.

The Department of Health currently also regulates that:

- All the results of antibody testing conducted must be recorded and reported to the National Health Laboratory Service (NHLS), utilising the appropriate application (found at: <https://csa.nhls.ac.za/>).
- Rapid antibody tests, when utilised, should only be administered by suitably qualified and trained health professionals.
- Laboratory-based serology testing should be conducted in ISO15189 accredited facilities only.

Should antibody testing be used to determine which individuals are safe to return to the workplace?

It should be noted that there is currently not sufficient evidence to correlate the detection of antibodies with immune protection. A positive antibody test result should therefore not be regarded as proof of immunity and must not be used to reduce or abandon protective measures. The issuing of an "immunity passport" or "immunity certificate" based on a positive antibody test result is not currently recommended by the South African Department of Health or by the WHO.

Is there cross-reactivity with SARS-CoV and other Coronaviruses?

Antibody assays are designed to have no or very limited cross-reactivity to other circulating viruses and validation data confirms this. As testing experience is limited at this stage, the exact specificity of these tests will be informed over time.

Does the immune response differ in immunocompromised patients and children?

Most of the available data was obtained in adult populations who are not immunocompromised. Many questions still remain and need to be studied in these different patient groups.

When will antibody testing be available?

PathCare will commence antibody testing when all approvals are in place and will communicate this date by SMS. Our private rate for the test is R224.10 (including VAT), and usual policies for cash payments and senior citizens will apply. The test will have a turn-around time of 24 hours from Gauteng or the Western Cape, and 48 hours elsewhere. Please submit a serum (SST) or EDTA plasma sample for this test.

Compiled by Dr Louis Marcus and the virologists from PathCare.

Further Reading

Department of Health, Republic of South Africa. Aug 24th, 2020. Guidance on the use of SARS CoV-2 Antibody Tests. <https://sacoronavirus.co.za/2020/08/24/guidance-on-the-use-of-sars-cov-2-antibody-tests/>

Centers for Disease Control and Prevention. 2020. Serology Testing for COVID-19 at CDC. <https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html>. Chen, Y & Li, L. 2020. SARS-CoV-2: Virus Dynamics and Host Response. Lancet Infectious Diseases. 20(5), 515-516.

Hagen, A. 2020. Tests for SARS-CoV-2/COVID-19 and Potential Uses. American Society for Microbiology. <https://mbio.asm.org/content/11/2/e00722-20>.

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