

MD003: Testing for COVID-19

In line with the recommendation of the South African National Institute for Communicable Disease (NICD)¹ and the recommendation of the World Health Organization (WHO)² the use of serological tests are not currently recommended for the clinical diagnosis of COVID-19.

TESTS USED TO TEST FOR COVID-19³

1. COVID-19 is the disease caused when a person is infected by a new coronavirus called SARS-CoV-2.
2. A test can be performed to determine if a person has been infected with SARS-CoV-2 and has the COVID-19 virus.
3. There are two kinds of tests that can be used:
 - a. Tests that detect the presence of the actual SARS-CoV-2 virus in your body (molecular tests). This test is done by taking a swab of your nose or mouth in order to test if the virus is present in your nasal secretions (snot) or sputum (saliva/spit).
 - b. Tests that detect whether your body has produced antibodies to the SARS-CoV-2 infection (serological tests). This is usually done by taking a sample of your blood and testing your blood for specific antibodies.

MOLECULAR TESTS -DETECTING THE PRESENCE OF SARS-CoV-2 VIRUS³

4. These tests detect the presence of the genetic material, called nucleic acids, of the actual SARS-CoV-2 virus. Such tests are good at detecting the virus early in the infection and can sometimes even detect the virus in a person before they become unwell.
5. Nucleic acid tests are complicated to do and usually need specialist scientists to run the tests in a laboratory to get an accurate result. The laboratory scientists can sometimes run these tests on automated machines that can do many tests at once. This means that you can test lots of people quickly.
6. There are now some SARS-CoV-2 nucleic tests available that can be used outside of a laboratory by trained people. Most of these systems give results quickly but cannot do many tests at once.

SEROLOGICAL TESTS - DETECTING ANTIBODIES TO THE SARS-CoV-2 VIRUS³

7. These tests look in our blood to see if our body has started fighting a SARS-CoV-2 infection, rather than detecting the actual SARS-CoV-2 virus. They do this by seeing if our blood contains specific antibodies that attach to parts of the virus.
8. It takes time for our bodies to make antibodies, so people can already have the SARS-CoV-2 virus and be spreading the infection to other people before we can detect their antibodies.
9. Scientists usually run viral antibody tests in laboratories, however since the beginning of the COVID-19 pandemic, a number of manufacturers have developed tests that can be used outside of the laboratory at the point of care. These are called rapid or point-of-care tests (POCT). You might also hear these tests called IgG or IgM tests. IgG and IgM are different kinds of antibodies that are made by our bodies to fight infection.

10. Serological tests that are being offered for the diagnosis of COVID-19 are not suitable for the diagnosis of COVID-19. They are not helpful to guide decision making regarding patient management, decisions regarding the need for quarantine, isolation or contact tracing.
11. These POCT antibody tests are not intended for self-testing. They are designed to be used under the direct supervision of a health care professional.

REGULATORY REQUIREMENTS FOR COVID-19 TEST KITS

12. At this moment in time, diagnosis of COVID-19 should be made by diagnostic tests (molecular tests) that detect the COVID-19 virus itself or genetic material from the virus, not by serological tests.
13. It is a contravention of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and as such illegal for someone to sell you a serological test claiming that you can test yourself at home or test yourself under the supervision of health care professional to determine whether or not you have a COVID-19 infection.
14. In South Africa, only companies that are licensed by SAHPRA may manufacture, import or sell diagnostic tests.

HOW CAN I GET TESTED FOR COVID-19³

15. As you can see from the above information, it is complicated to accurately detect a SARS-CoV-2 infection.
16. This is why we need to make sure that the diagnosis of COVID-19 is done using molecular testing, under the supervision of a health care professional. The health care professional can provide you with appropriate advice and treatment if required and importantly, the health care professional can alert the relevant health authorities. This way we can trace infections and take action to stop further spread of the infection.
17. Please see the SAHPRA website for updates relating to COVID-19 (www.sahpra.org.za).
18. Please report any company/individual/website selling COVID-19 serological test kits to the Regulatory Compliance Unit of SAHPRA so that SAHPRA may take action in this regard.

REFERENCES:

1. South African National Institute for Communicable Disease (NICD), Advice on the role of rapid/serological testing, published on the 27 March 2020
2. World Health Organization (WHO) (Laboratory testing strategy recommendations for COVID-19. WHO Interim guidance, published on the 22 March 2020
3. <https://www.tga.gov.au/how-testing-works-covid-19>, accessed 27 March 2020

DR B SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER OF SAHPRA
22 JULY 2020