SAHPRA
South African
Health Products
Regulatory Authority

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Communication to Stakeholders 30 March 2020

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], serological tests that are being offered for the diagnosis of COVID-19 are not suitable for the diagnosis of COVID-19 at the acute stage. They are not helpful to guide decision making regarding patient management, decisions regarding the need for quarantine, isolation or contact tracing at the point of the pandemic in the country.[1]

TESTS USED TO TEST FOR COVID-19[3]

1. COVID-19 is the disease caused when a person is infected by the novel coronavirus called SARS-CoV-2.
2. An *in vitro* diagnostic test can be performed to determine if a person has been infected with SARS-CoV-2 and therefore has COVID-19.
3. Two different types of *in vitro* tests are possible:
    a. Tests that detect the presence of the SARS-CoV-2 virus (molecular tests). These tests are performed on material obtained by means of nasopharyngeal and oropharyngeal swabs.
    b. Tests that detect antibodies to the SARS-CoV-2 virus (serological tests). These tests are conducted on finger-pick blood samples.

MOLECULAR TESTS -DETECTING THE PRESENCE OF SARS-CoV-2 VIRUS[3]

4. These tests detect the presence of genetic material (nucleic acids) of the actual SARS-CoV-2 virus. Such tests are good at detecting the virus early in the infection and can detect the virus in a person before they become unwell.
5. Nucleic acid tests (reverse transcriptase polymerase chain reaction; RT-PCR) are laboratory-based tests, requiring access to specialised equipment. require the

SEROLOGICAL TESTS - DETECTING ANTIBODIES TO THE SARS-CoV-2 VIRUS[3]

6. Serological tests detect the presence of IGM and/or IgG antibodies to SAR-CoV-2.
7. These tests can be conducted at the point-of-care, as they rely on lateral flow methods and can be conducted on a small finger-prick blood sample.
8. Serological tests are not suitable for the diagnosis of COVID-19, as the period between acute infection and detection of antibodies is unknown at this time. They are not helpful to guide decision making regarding patient management, decisions regarding the need for quarantine, isolation or contact tracing.

REGULATORY REQUIREMENTS FOR COVID-19 TEST KITS

9. At this time, diagnosis of COVID-19 should be made by means of approved molecular diagnostic tests, not by serological tests.
10. The sale of serological tests, whether for self-testing or testing under the supervision of healthcare professional is not advised.
11. In South Africa, only companies that are licensed by SAHPRA may manufacture, import or sell diagnostic tests.

HOW CAN I GET TESTED FOR COVID-19[3]

12. All COVID-19 testing must be done using molecular testing, under the supervision of a healthcare professional, by an accredited public or private sector laboratory.
13. Please see the SAHPRA website for updates relating to COVID-19 (www.sahpra.org.za).
14. Please report any company/individual/website selling COVID-19 serological testing kits to SAHPRA so that the necessary action can be taken in this regard.

REFERENCES:

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

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