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SPECIAL INTEREST GROUP OF THE SOUTH AFRICAN MEDICAL ASSOCIATION

25 March 2020.

Dear colleagues,

STATEMENT ON RAPID POINT-OF-CARE TESTS FOR COVID-19

It has been brought to the attention of the National Pathology Group (NPG) that many private laboratories as well as healthcare providers have been approached by companies who distribute rapid point-of-care serological tests for COVID-19 detection.

The current so-called gold standard for detection of the SARS-2 Coronavirus detection (the virus that causes COVID-19) is by means of molecular detection with a PCR assay. All the laboratories in South Africa currently use this method for detection of COVID-19. There is a global anticipation that the testing demand for COVID-19 will increase, and as such additional test methods are being developed. It should be noted that, despite this demand, there is still too little known regarding antibody responses to COVID-19, the overall sensitivity of these tests, and how these can be utilized clinically.

As in the case of influenza, the delayed antibody response may limit the use of rapid tests to diagnose acute infection. Whether this will be the case with COVID-19 is still unknown. There may well be a risk of serology tests producing false negative results within the early phase of infection.

Antibody tests are in general prone to cross-reactive reactions due to other antibodies circulating, which may well be the case if patients had prior coronavirus infections with common human coronaviruses which circulate in the population. The specificity of these assays need to be determined prior to use.

All confirmed cases of COVID-19 are currently notifiable, thus rapid test results would currently require confirmation by means of a formal laboratory PCR, whether positive or negative. Use of rapid tests may prove detrimental to managing cases, especially in the case of false negative results, where isolation might be forsaken.

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The World Health Organization (WHO) states the following (World Health Organization. Laboratory testing strategy recommendations for COVID-19: Interim guidance. WHO/COVID-19/lab testing/2020.1):

"Serological assays will play an important role in research and surveillance but are not currently recommended for case detection and are not included in this document. The role of rapid disposable tests for antigen detection for COVID-19 needs to be evaluated and is not currently recommended for clinical diagnosis pending more evidence on test performance and operational utility. WHO will update this guidance as more information on laboratory tests for COVID-19 becomes available."[1]

The NPG agrees that new testing approaches should be explored during this global pandemic. However, there is insufficient evidence and experience with these rapid tests now. As such the NPG does not currently recommend the use of rapid point-of-care serology tests for the diagnosis of COVID-19, nor does it consider these tests to be appropriate for determining a patient's exposure history or potential immunity to the SARS-2 Coronavirus. The NPG members intend to evaluate these tests, and will provide further guidance should it be necessary.

Yours sincerely,

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