THE PATHCARE NEWS

PathCare SARS-CoV-2 / COVID-19 testing:

31/03/2020 update

At the time of writing, **COVID-19 is still a Category 1 Notifiable Condition and the suspicion of the disease must be notified through the Notifiable Medical Conditions (NMC) system, as for other notifiable diseases. PathCare requires a completed Person Under Investigation (PUI) form and contact line list,** which can be obtained from the PathCare website under "Documentation" (pathcare.co.za). In addition to the PUI form, a completed PathCare request form must be supplied with either "COVID-19" or "SARS-CoV-2" as the requested test. Please ensure that the patient's mobile phone number, a second contact number (mobile number preferably) and physical address are included on the form as this will be necessary for contact tracing.

As per the NICD, PathCare will not be processing asymptomatic patients for coronavirus testing. The official NICD case definition was updated on 25/03 and will be adhered to; please see the accompanying NICD Quick Reference Guide. The reasons for testing only symptomatic individuals are that the PCR may be negative prior to development of symptoms in patients with COVID-19 and that inappropriate testing may rapidly saturate available testing capacity. Asymptomatic patients with a history of exposure or international travel should self-isolate for 14 days.

In symptomatic patients, a combination of nasopharyngeal and oropharyngeal swabs may be submitted for testing or samples taken from the lower respiratory tract. If patients are referred to PathCare depots for swabs to be taken, we request that any symptomatic patient be supplied with a surgical mask that is worn before the patient enters the depot in order to protect vulnerable patients. If possible, please also alert the depot of the patient's arrival. **If you refer patients to a PathCare depot for swabs to be taken, patients must have physical copies of the PUI form and PathCare request form with them when presenting for sampling.**

Many rapid serological tests have also been offered to clinicians over the past few weeks. Please note that the use of these devices is not supported for the diagnosis of COVID-19 by the WHO, SAHPRA or the National Pathology Group, and the NPG statement will accompany this letter.

We would also like to reinforce the use of influenza vaccines to reduce the impact of respiratory diseases in our winter season. It is recommended that all healthcare workers receive influenza vaccination, but any patient who does not have a contraindication for vaccination should be considered for a vaccine.

If further information is required, please visit PathCare's website or the NICD's website at http://www.nicd.ac.za/diseases-a-z-index/covid-19/covid-19-resources/. The virologist on call can also be contacted through PathCare's switchboard at 021 596 3400.

NATIONAL INSTITUTE FOR COMMUNICABLE DISEASES
Division of the National Health Laboratory Service

Coronavirus disease 2019 (COVID-19)
Quick Reference for Health Workers

25 March 2020

National Institute for Communicable Diseases (NICD)
24-hour hotline number: 0800 11 1131|066 562 4021

Background

On the 31st December 2019, the World Health Organization (WHO) China country office reported a cluster of pneumonia cases in Wuhan City, Hubei Province of China now known to be caused by a novel virus. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been confirmed as the causative virus of coronavirus disease 2019 (COVID-19). Cases have now been identified in over 100 countries including South Africa and WHO has declared a global pandemic.

Clinical presentation and management of suspected cases

The main clinical signs and symptoms are fever and cough with a few patients presenting with difficulty in breathing and bilateral infiltrates on chest X-rays. Lymphopenia may be present. Treatment is supportive. The differential diagnosis for this syndrome is broad. Consider the possibility of influenza (Southern Hemisphere influenza season will begin in May or June), bacterial pneumonia, tuberculosis, *Pneumocystis jirovecii* (PCP) if immunosuppressed, and manage accordingly.

Criteria for person under investigation (PUI), i.e. a person to be tested for COVID-19

A **hospitalised** patient with severe acute respiratory illness (fever and at least one sign/symptom of respiratory disease, e.g., cough, shortness of breath) AND the absence of an alternative diagnosis that fully explains the clinical presentation

OR

Any person with acute respiratory illness with sudden onset of at least one of the following: cough, sore throat, shortness of breath or fever [≥ 38°C (measured) or history of fever (subjective)] irrespective of admission status **AND**

In the 14 days prior to onset of symptoms, met at least one of the following epidemiological criteria:

Were in close contact[1] with a confirmed[2] or probable[3] case of COVID-19;
OR
Had a history of travel outside of South Africa;
OR
Worked in[4] or attended a health care facility where patients with SARS-CoV-2 infections were being treated.

[1]Close contact: A person having had face-to-face contact (≤1 metre) or in a closed space with a COVID-19 case for at least 15 minutes. This includes, amongst others, all persons living in the same household as a COVID-19 case and, people working closely in the same environment as a case. A healthcare worker or other person providing direct care for a COVID-19 case, while not wearing recommended personal protective equipment or PPE (e.g., gowns, gloves, NIOSH-certified disposable N95 respirator, eye protection). A contact in an aircraft sitting within two seats (in any direction) of the case, travel companions or persons providing care, and crew members serving in the section of the aircraft where the case was seated.
[2]Confirmed case: A person with laboratory confirmation of SARS-CoV-2 infection (using an RT-PCR assay), irrespective of clinical signs and symptoms. Symptomatic cases are considered infectious from 2 days before symptom onset to 14 days after symptom onset.
[3]Probable case: A PUI for whom testing for SARS-CoV-2 is inconclusive (the result of the test reported by the laboratory) or who tested positive on a pan-coronavirus assay.
[4]Working in a health care facility includes healthcare workers as well as administrative and support staff such as cleaning staff

Infection prevention and control (IPC)

1. Early detection is key - health care workers should maintain a high level of clinical suspicion
2. Patients should be asked to wear a surgical mask once identified and be evaluated in a private room
3. Isolate PUI
4. Use appropriate infection control for PUI
    a. Standard precautions for all patients
    b. Add contact and droplet precautions for all PUI
    c. Airborne precautions (e.g., N95 mask) and eye protection must be used when performing aerosol-generating procedures
    d. If available, airborne precautions can be used at all times
    e. Limit patient movement (e.g., portable X-ray)

Specimen collection for SARS-CoV-2 testing

Collect appropriate samples. **Lower respiratory tract samples are preferred because the lower respiratory tract is the primary site of infection.**

- Combined nasopharyngeal and oropharyngeal swabs in ambulatory patients and sputum (if produced) and/or tracheal aspirate or bronchoalveolar lavage in patients with more severe respiratory disease.
- Use universal/viral transport medium for swabs, if available; sterile container for sputum and aspirates; see page 2 for sample collection instructions.

A single negative test result, especially if from upper respiratory tract specimen, does not exclude infection. Repeat sampling and testing of lower respiratory tract samples is recommended for case with severe disease or in whom COVID-19 is strongly suspected.

Case notification

COVID-19 is classified as a Class 1 notifiable medical condition. Therefore, notification should be made immediately to the district or provincial communicable disease co-ordinators (CDCCs) on identification of a person meeting the definition for person under investigation (PUI) for COVID-19, a cluster of cases with severe respiratory illness with evidence of common exposure or epidemiologic link, or on receipt of a laboratory diagnosis of COVID-19. More details can be found here. District or provincial CDCCs are to notify the NICD. Contact tracing will be initiated for confirmed COVID-19 cases.

COLLECTION OF NASO/OROPHARYNGEAL SWABS FOR DETECTION OF RESPIRATORY VIRUSES:

Respiratory viruses are best isolated from material that contains infected cells and secretions. Therefore, swabs should aim to brush cells and secretions off the mucous membranes of the upper respiratory tract. ***Good specimen quality*** (i.e. containing sufficient cells and secretions) and appropriate ***packaging and transport*** (i.e., to keep virus viable/detectable) are essential.

Step 1: Equipment and materials

1. Complete specimen submission form **and** person under investigation (PUI) form **and** contact line list found here
2. Nasopharyngeal (NP) & oropharyngeal (OP) flocked swabs
3. Tube containing universal transport medium (UTM), if UTM unavailable may use gel or send dry in sterile tube
4. Tongue depressor
5. Gloves
6. Surgical mask
7. Tissue for the patient to use after sample collection
8. Biohazard bag for disposal of non-sharp materials
9. Cooler box and cooled ice packs
10. Ziploc plastic specimen bag

Step 2: Record keeping

1. Complete the specimen submission form **and** person under investigation (PUI) form **and** contact line list
2. Place specimen submission and PUI form into a Ziploc bag
3. Label the tube of universal transport media (UTM) with the patient's name and date of birth and sample type

Step 3: Collection of nasopharyngeal swab (NPS)

1. Don a pair of gloves and a surgical mask
2. Open a sterile flocked swab at the plastic shaft
3. Ask the patient to tilt his/her head back. Estimate the distance from the patient's nose to the ear. The swab should be inserted one-half to two-thirds of this distance.
4. Gently insert swab into the nostril and back (not upwards) to the nasopharynx until a slight resistance is met
5. Rotate swab 2-3 times and hold in place for 2-3 seconds
6. If resistance is met before fully inserted, remove and try the other nostril
7. Slowly withdraw the swab and put it into the specimen container
8. Break plastic shaft at the break point line & close the tube

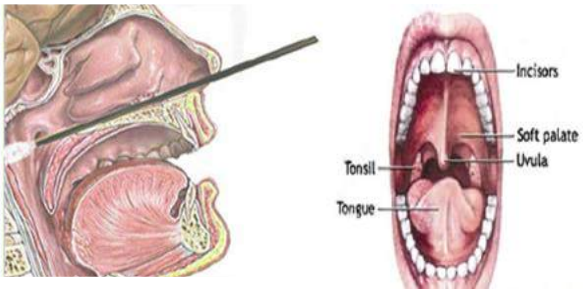
Step 4: Collection of oropharyngeal swab (OPS)

1. Keeping the same pair of gloves on, and holding the UTM with the nasopharyngeal swab in, take a second flocked swab and open it at the plastic shaft
2. Ask the patient to tilt their head back and mouth open
3. Hold the tongue down with a tongue depressor
4. Have the patient say "aahh" to elevate the uvula
5. Swab each tonsil first, then the posterior pharynx in a "figure 8" movement
6. Avoid swabbing the soft palate or the tongue with the swab tip as this can induce the gag reflex
7. Place the swab into the same UTM tube with the NPS already in and break off the shaft at the break point
8. Tightly close the tube
9. Place the closed tube with two swabs in the Ziploc bag
10. Remove gloves and mask then wash hands thoroughly

Step 5: Transport of specimens

1. Ensure the cooler box and ice packs stay at 2-8^{0}C
2. Transport to NHLS or private laboratory on the day of specimen collection
3. Contact NHLS laboratories as below for shipping instructions or contact private laboratories directly
4. If shipping to NICD (for reference testing), mark: "Suspected COVID-19, NHLS/NICD, Centre for Respiratory Diseases and Meningitis (CRDM), Lower North Wing, SAVP building 1 Modderfontein Rd, Sandringham, Johannesburg, 2131".
5. NHLS laboratories use usual overnight regional courier service; private labs will ship via existing systems

Diagram: How to collect a nasopharyngeal swab (left) and oropharyngeal swab (right)



Step 6: NHLS laboratory contact details

Eastern Cape Province:	
Dora Nginza Virology Lab	
Dr Howard Newman	0413956152
Free State Province:	
Universitas Virology	051 405 3162
After hours ask for virologist on call	051 405 3033
Gauteng Province:	
Charlotte Maxeke Laboratory	082 329 2914
Tshwane Virology Laboratory	
Prof Sim Mayaphi	012 319 2351
DGM Virology Laboratory	
Dr Temitayo Famoroti	012 521 4398
KwaZulu Natal Province:	
Inkosi Albert Luthuli Academic Hospital Virology	
Dr Khanyisile Msomi	031 240 2791/4
Northern Cape Province:	
Universitas Virology	051 405 3162
After hours ask for virologist on call	051 405 3033
Western Cape Province:	
Tygerberg Virology	021 938 4330/4934
Groote Schuur Hospital Virology	021 404 4129/3091

Please refer to www.nicd.ac.za for most recent version of this document before use.

Version 9, 25 March 2020

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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.

P. O. Box 803 Florida Hills 1716 South Africa • Tel + 27 (11) 472 0628 • Fax + 27 (11) 472 0668 • npg@mweb.co.za • www.npg.co.za

Association incorporated under section 21, Reg. No. 1927 / 000136 / 08

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SPECIAL INTEREST GROUP OF THE SOUTH AFRICAN MEDICAL ASSOCIATION

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,

Dr. M. Forder	Dr. P. Cole	Dr. J. Douglass
CEO	CEO	CEO
Ampath	Lancet Laboratories	Pathcare

P. O. Box 803 Florida Hills 1716 South Africa • Tel + 27 (11) 472 0628 • Fax + 27 (11) 472 0668 • npg@mweb.co.za • www.npg.co.za

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MEDIA RELEASE

COVID-19 – The Appropriate place for Rapid Test Kits

Embargo: Immediate release

Pretoria, 30 March 2020 - In line with the recommendation of the South African National Institute for Communicable Disease (NICD) and the recommendation of the World Health Organization (WHO), SAHPRA wishes to point out that the so-called **Rapid test kits (serological test kits)** that are being offered for the diagnosis of COVID-19 are not suitable for this purpose. They are not helpful to guide decision-making regarding patient management, decisions around the need for quarantine, isolation or contact tracing. Serological tests are used for epidemiological surveys, but not for the diagnosis of acute infections.

CLARITY ON COVID-19

COVID-19 is the disease caused when a person is infected by the novel coronavirus called SARS-CoV-2. A test can be performed to determine if a person has been infected with the **SARS-CoV-2** virus and has the **COVID-19** disease. There are **two** types of tests that can be used:

1) Molecular (or PCR test): Tests that detect the presence of the actual SARS-CoV-2 virus in your body by detecting the genetic material of the actual virus (molecular tests). This test is done by taking a swab from your mouth or nose. This test is complicated and needs to be done in a laboratory. These tests can detect the virus even before a patient becomes unwell.
2) Serological tests (or Rapid Test) Tests that detect whether your body has produced antibodies to the SARS-CoV-2 infection (serological tests). This is done through a finger-prick blood test It takes many days for the body to develop antibodies against the virus so people can already

have the SARS-CoV-2 virus and can be spreading the infection to other people but we would not be able to detect their antibodies.

RAPID TEST KITS

Since the beginning of the COVID-19 pandemic, a number of manufacturers have developed tests that are referred to as Serological, Rapid or Point of Care (PoC) tests. They are sometimes referred to as IgG or IgM tests. These rapid and PoC tests (serological) are not intended for **diagnosis of acute infections** and should not be relied upon for self-testing as they may be interpreted as meaning that someone is not infected with the virus when they may actually be infected already. These tests are designed to be used under the direct supervision of a **health care professional** in epidemiological surveys.

"It is vital that all COVID-19 tests should be conducted by a health care professional and processed by a certified laboratory to ensure accuracy of decision-making, treatment and advice. The health care professional can also decide on whether to alert the relevant health authorities and conduct contact tracing. This will ensure that authorities can trace infections and take action to stop further spread of the infection. The South African public is reminded that at this stage, the use of serological test kits is not recommended. The public is discouraged from using rapid test kits (serological), 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. Furthermore, all tests and establishments manufacturing or distributing such tests should be licensed by SAHPRA," indicates **SAHPRA CEO**, Dr Boitumelo Semete-Makokotlela.

SAHPRA has implemented an expedited licence process for new applications and amendments to current licences in order to support the supply of medical devices that may be required in response to the COVID-19 pandemic.

SAHPRA appeals to the public to report to SAHPRA any company/individual/website selling COVID-19 Rapid test kits so that SAHPRA can take the necessary action in this regard. Please provide the details to the Law Enforcement Unit (Contact information listed below).

Issued by:

Dr Boitumelo Semete

CEO

For further enquiries /information contact:

Media contact:

Mr Yuven Gounden

Tel: 012 842 7628

Cell: 083 297 1214

E-mail: yuveng@sahpra.org.za

SAHPRA Medical Devices:

Ms Andrea Julsing

Cell: 082 062 2594

Email: andrea.julsing@sahpra.org.za

SAHPRA Law Enforcement

Ms Daphney Fafudi

Cell: 066 3011878

Mokgadi.fafudi@sahpra.org.za

About SAHPRA:

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines, medical devices and in-vitro diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 15 of 1973).

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of all who reside in South Africa:

- Safety

- Efficacy
- Quality

It is these three pillars that define the ethos of SAHPRA.