2 TESTING

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FOREWORD

These guidelines are a revision of the "Guide to antigen testing for SARS-COV-2 in South Africa" issued in July 2021. This document is intended for use by health care professionals in the management of Covid-19 in South Africa.

This new document provides guidance on diagnostic tests available, on antigen test performance and accessibility like the previous guide. However, there are new issues covered such as the use of antigen self-tests update on testing eligibility and revision of guidance on reporting of results.

Clinical management of Covid-19 is addressed in a separate document. All efforts have been made to find and use the most recent scientific evidence in the compilation of these guidelines.

The National Department of Health would like to acknowledge the technical team that put these guidelines together.

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Director General: Health
Date: 09/01/2023

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COVID-19 TESTING

1. INTRODUCTION

As the COVID-19 pandemic evolves to become more endemic, the Department of Health recommends a more targeted testing approach and reviews the more recent methods of testing e.g. COVID self -testing that is used in many other countries.

1.1 WHAT'S NEW?

- Guidance on the use of antigen self-tests
- Update on testing eligibility
- Revision of guidance on reporting of results

2. WHO SHOULD BE TESTED FOR COVID-19?

The following categories of people should be tested:

Individuals **SUSPECTED of having COVID-19 AND** any of the following:

1. Who are admitted to hospital. At times when resources are constrained, individuals with pneumonia and are admitted to ICU or high care should be prioritized for testing.
2. Who are at high risk of severe disease (those aged >40 years; those of any age who have one or more of the following co-morbidities: diabetes, obesity, heart disease, lung disease, kidney disease, cancer, tuberculosis, poorly controlled HIV and immunocompromised individuals)
3. Who are awaiting surgery (should be tested 3 days or less before surgery)
4. Health care workers and care home workers in high risk settings
5. As part of the diagnosis of multisystem inflammatory syndrome in children (MIS-C)
6. When advised by a health care professional

Testing may also be indicated for:

- Individuals with COVID-19 symptoms for infection control in congregant settings such as care homes and hospitals
- Travelers with COVID-19 symptoms for infection control in the aircraft
- Disease surveillance research programmes, such as syndromic respiratory illness surveillance and post mortem screening

Individuals with COVID-19 symptoms that do not meet the criteria for testing should be advised for the next 5 days to wear a mask, avoid social gatherings and avoid socially interacting with the elderly (>60 years) or anyone with co-morbidities.

3. WHICH TESTS ARE INDICATED FOR THE DIAGNOSIS OF COVID-19?

To diagnose acute COVID-19, viral tests are used which detect either SARS-CoV-2 (i) nucleic acid (PCR) or (ii) proteins (antigen tests). Reverse transcription real time PCR (RT-PCR) is a laboratory test, while an antigen test (Ag-RDT) can be performed at point-of-care or at home (self-test). Only tests that have received SAHPRA approval should be used. There are advantages and disadvantages to both testing modalities (Table 1).

Table 1: Evaluation framework for SARS-CoV-2 testing

Characteristics	RT-PCR test	Ag-RDT test
Sensitivity	• High sensitivity	• Less sensitive than RT-PCR and false-negative results can occur
Specificity	• High specificity	• High specificity
Turnaround times	• Longer turnaround times (1-3 days)	• Shorter turnaround times (15-30 minutes)
Cost	• Higher cost than Ag-RDT	• Lower cost than RT-PCR
Infrastructure requirements	• Requires laboratory facilities	• No laboratory needed, can be done at point of care or at home (self-test)
Benefits	• No follow up test required • Reliable for individuals with and without symptoms	• Faster identification of cases to reduce spread of COVID-19 • Greater access to testing, particularly in areas further away from RT-PCR labs • Predominantly only positive in patients who are infectious
Drawbacks	• May continue to be positive for several weeks after infection and may not accurately reflect shedding of infectious virus	• Smaller window of detection (within 7 days of symptom onset) • Most useful in symptomatic individuals • Where the pretest probability is high, a negative result may need to be followed by a RT-PCR test

Currently, RT-PCR and Ag-RDT tests in use in South Africa can detect all known variants and lineages of SARS-CoV-2. While PCR tests remain the reference standard, antigen tests provide a quicker turnaround time and are cheaper. However, they are less sensitive than PCR-based assays and may require a follow-up test.

Ag-RDT play an important role as they enable decentralised testing and thereby increase access to testing. Self-testing using Ag-RDTs can provide real-time information and empower individuals to know their COVID-19 status and take individual-level actions accordingly. Self-testing for both vaccinated and unvaccinated individuals can be an efficient way to limit the spread of COVID-19 and therefore self-testing should be encouraged. There are currently no self-test kits approved by SAHPRA. When self-test kits are approved, a list of approved tests will be available on the SAHPRA website. As with all Ag-RDT tests, a negative doesn't exclude COVID-19 infection.

4. SARS-COV-2 RT-PCR TESTS

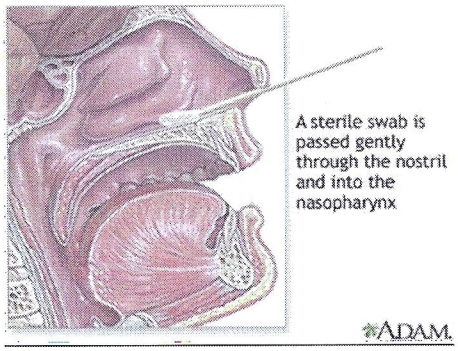
Recommended sample types for SARS-CoV-2 RT-PCR tests include nasopharyngeal, mid-turbinate, anterior nares (nasal) or oropharyngeal swabs. Lower respiratory tract samples such as sputum, tracheal aspirates or bronchoalveolar lavage fluid are also acceptable samples. Sputum induction should not be performed.

4.1 SAMPLE COLLECTION

- Healthcare workers collecting respiratory samples require appropriate personal protective equipment, including eye protection (goggles or visor), gloves, an apron or gown, and an N95 respirator (or equivalent, e.g. FFP2 mask). Meticulous hand hygiene is also essential (see Module 9: Infection prevention and control).
- Collecting a good-quality specimen is vital – see Figure 1.
- Appropriate swabs for RT-PCR are flocked or spun, and consist of polyester, nylon or rayon material with a plastic or aluminium shaft. Cotton swabs, calcium alginate swabs, and swabs with a wooden shaft are not recommended, as they may contain substances that inhibit PCR testing.

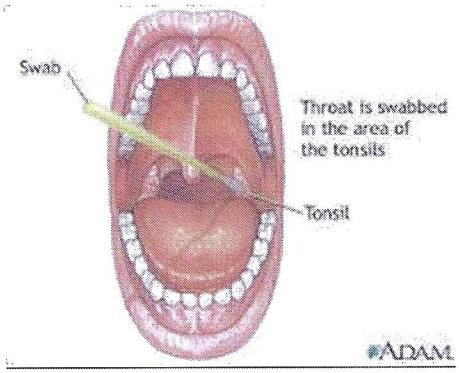
Collection of a nasopharyngeal specimen

1. Ask the patient to tilt his/her head back slightly.
2. Gently insert swab into the nostril, aiming backwards (not upwards) until a slight resistance is met – about the distance from the nose to the anterior ear. If resistance is met before fully inserted, remove and try the other nostril.
3. Rotate swab 2-3 times and hold in place for 2-3 seconds.
4. Slowly withdraw the swab and put into the specimen tube containing universal transport medium.
5. Break the swab's shaft and close the tube.



Collection of an oropharyngeal specimen

1. Ask the patient to tilt his/her head back and open their mouth.
2. Hold the tongue down with a tonguedepressor.
3. Have the patient say "aahh" to elevate the uvula.
4. Swab each tonsil first, then the posterior pharynx in a "figure 8" movement.
5. Avoid swabbing the soft palate or the tongue as this can induce the gag reflex.
6. Break the swab's shaft and close the specimen tube tightly.



Collection of a mid-turbinate specimen

1. Ask the patient to tilt his/her head back slightly.
2. Gently insert swab less that 2cm into the nostril (unless resistance is met at the turbinates).
3. Gently rotate the swab several times against the nasal wall.
4. Repeat in the other nostril, using the same swab.
5. Withdraw the swab and put it into the specimen tube containing universal transport medium.
6. Break the swab's shaft and close the tube.

Collection of an anterior nares (nasal) specimen

1. Ask the patient to tilt his/her head back slightly.
2. Insert the swab at least 1cm inside the nares.
3. Firmly sample the nasal membrane by rotating the swab and leaving it in place for 10-15 seconds.
4. Sample both nares with the same swab.
5. Withdraw the swab and put it into the specimen tube containing universal transport medium.
6. Break the swab's shaft and close the tube.

Figure 1: Specimen collection for SARS-CoV-2 RT-PCR testing

4.2 TRANSPORT OF SPECIMENS

- For PCR testing, swabs should ideally be placed in viral/universal transport medium (VTM/UTM) and kept between 2-8°C until they are processed at the laboratory. Dry swabs can be sent at ambient temperature provided that the sample reaches the laboratory within two days. Please confirm conditions with your laboratory.
- Lower respiratory tract samples can be sent in standard specimen containers and do not require viral/universal transport medium.

Samples should be submitted with a laboratory request form containing complete and accurate patient information needed for notifiable medical conditions:

- Name and surname
- Sex
- Date of birth
- Address
- Cell phone number
- ID or passport number

A single positive PCR test is sufficient proof of COVID-19. There is no role for repeat 'confirmatory' PCR testing on patients who test positive despite the absence of symptoms. PCR has excellent specificity, and asymptomatic and pre-symptomatic COVID-19 patients are well described.
Inconclusive results need to be interpreted in the light of clinical circumstances. A repeat sample obtained a few days later often helps resolve doubtful cases.

5. SARS-COV-2 RAPID ANTIGEN TESTS

Rapid antigen (Ag-RDT) tests are highly specific but less sensitive than PCR tests. Thus false-negative results may occur. While a considerable proportion (up to 30% and more) of PCR-positive samples may be missed by rapid antigen tests, these are usually samples with low viral loads (high Ct values on PCR) and thus from patients who are unlikely to be highly infectious.

- **A positive antigen test result confirms infection**.
- The interpretation of a negative rapid antigen test result depends on the pre-test probability of a patient having COVID-19.
- Symptomatic individuals that test negative by antigen test should be evaluated to determine if they need to have a sample collected for PCR test immediately at the same visit. All rapid antigen tests use proprietary specimen buffers, which may not be suitable for subsequent testing by PCR. If PCR is required, a fresh sample should be collected.

5.1 SAMPLE COLLECTION

For sample collection of Ag-RDT testing, refer to package insert of antigen kit.
For Ag-RDT self-testing, refer the patient to CDC video on how to collect a swab.

For testing performed outside of the healthcare environment, patients should be advised to strictly adhere to the kit instructions on sample collection, test performance and reading of test results. **Not following the kit instructions may result in poor performance of the test / the incorrect result.**

6. SARS-COV-2 ANTIBODY TESTS

Antibody-based (serological) tests should not be used to diagnose acute COVID-19. Antibody tests provide evidence of previous infection with SARS-CoV-2. These tests are insufficiently sensitive early in the disease course (before sufficient antibodies have been produced, which often takes two weeks or longer after symptom onset).[1,2] Antibody-based tests may have a role in other scenarios, such as seroprevalence surveys or the diagnosis of Multisystem Inflammatory Syndrome in Children (MIS-C).

A positive antibody test result does not mean that a person has protection against SARS-CoV-2 infection. Antibody tests must be interpreted with caution in patients who have been vaccinated against COVID-19. Antibody tests targeting the spike (S) protein are expected to give positive results after vaccination (all current vaccines elicit antibodies against the spike protein) or previous SARS-CoV-2 infection. In contrast, antibody tests targeting the nucleocapsid (N) protein only give evidence of previous SARS-CoV-2 infection.

7. WHAT TO DO WHEN TESTED POSITIVE/NEGATIVE

If tested positive, an individual should isolate according to the Department of Health guidelines. Symptoms should be monitored, and healthcare sought if needed.

If tested negative, SARS-CoV-2 infection is unlikely. Symptoms could be due to another respiratory virus. Management should be guided by symptom severity. However, because false negative results can occur with rapid antigen tests, during surges in infection or if there is a high clinical probability of SARS-CoV-2 infection the result should be confirmed with an RT-PCR test.

8. REPORTING OF RESULTS

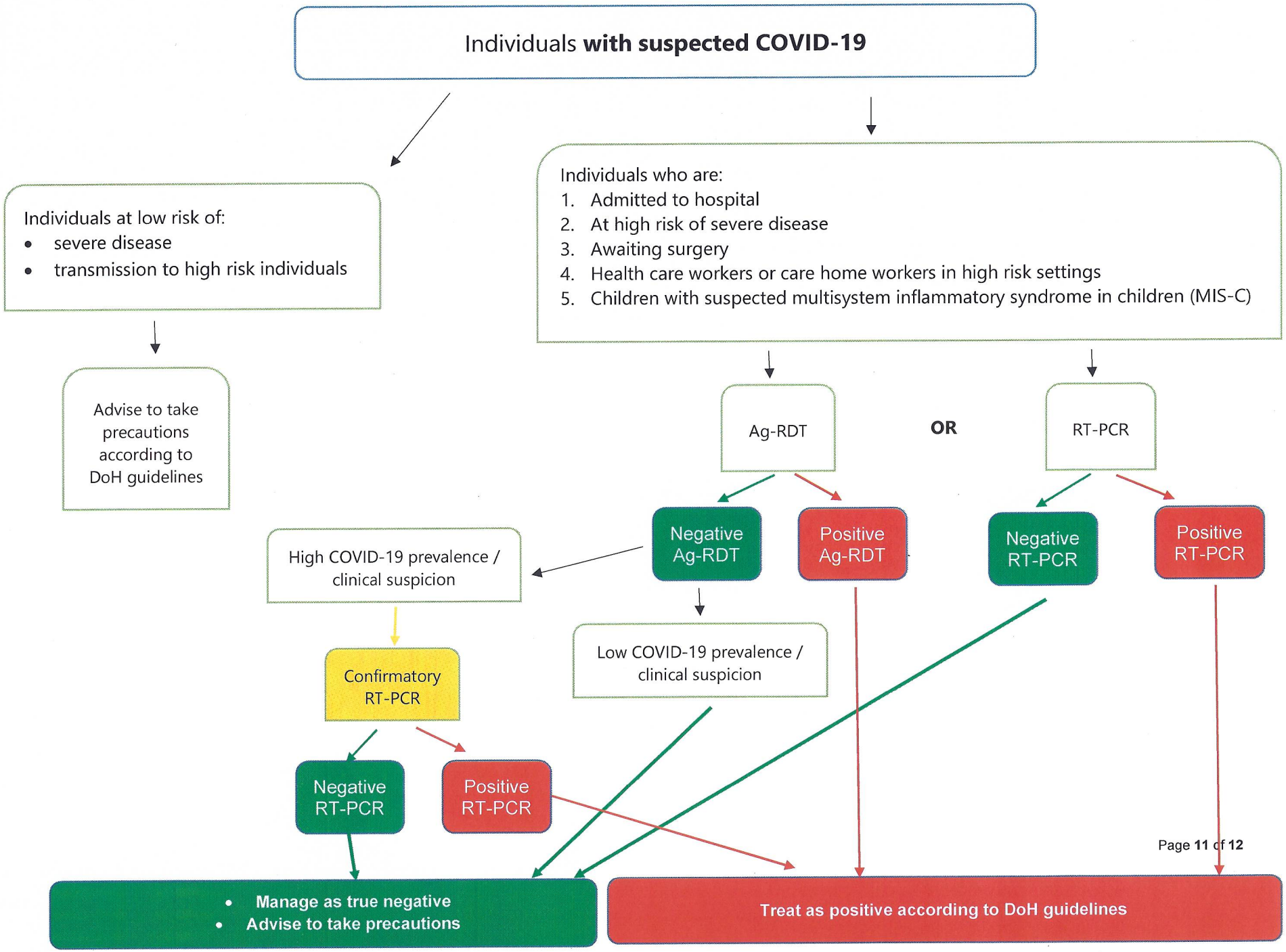
SARS-CoV-2 is a notifiable medical condition (NMC) that requires reporting of positive individuals by written or electronic notification to the National Department of Health NMC surveillance system by public and private healthcare providers, private health laboratories and public health laboratories.

Where testing has taken place in a laboratory, all positive SARS-CoV-2 tests must be

reported either using (i) the NHLS Laboratory Information System (Trakcare) where available, or (ii) directly downloaded from the laboratory information system (LIS) into the NICD API. Where a healthcare provider performs testing outside of a laboratory setting, positive SARS-CoV-2 tests must be reported to the NMC system (https://www.nicd.ac.za/nmc-overview/notification-process/).

To facilitate surveillance for new lineages of SARS-CoV-2, which requires sequencing of the viruses involved,[3] we recommend discussing the following scenarios with the virology laboratory or directly with the Network for Genomic Surveillance in South Africa.

- Prolonged shedding with high viral loads (i.e. low Ct values) in immunocompromised hosts.[4]
- Sudden increases in the COVID-19 caseload, increasing frequency of 'unusual' cases (e.g. in terms of disease presentation, patient groups affected, etc.) or the development of case clusters.[5]
- Possible animal-to-human spread.[6]
- Clinical suspicion of a change in the performance of diagnostic assays (PCR, antigen or antibody assays).
- Suspected cases of importation from another country, especially countries known to harbour virus variants of concern or countries with little available information.
- In addition, where most cases are diagnosed by rapid antigen tests, provisions need to be made for a certain proportion of positive samples to be referred for possible surveillance sequencing. Please observe national or regional specific advice/guidance.


Individuals with suspected COVID-19
Individuals at low risk of:
• severe disease
• transmission to high risk individuals
Advise to take precautions according to DoH guidelines
Individuals who are:
1. Admitted to hospital
2. At high risk of severe disease
3. Awaiting surgery
4. Health care workers or care home workers in high risk settings
5. Children with suspected multisystem inflammatory syndrome in children (MIS-C)
Ag-RDT
OR
RT-PCR
Negative Ag-RDT
Positive Ag-RDT
Negative RT-PCR
Positive RT-PCR
High COVID-19 prevalence / clinical suspicion
Low COVID-19 prevalence / clinical suspicion
Confirmatory RT-PCR
Negative RT-PCR
Positive RT-PCR
• Manage as true negative
• Advise to take precautions
Treat as positive according to DoH guidelines

9. REFERENCES

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