



Date:	04 March 2022		
To:	Dr MJ Phaahla, MP Honourable Minister of Health	From:	Ministerial Advisory Committee (MAC) on COVID-19

SARS-CoV-2 Antigen Self-Testing

Problem Statement and Task to Committee

Whether self-testing using SARS-CoV-2 antigen rapid detection tests (Ag-RDTs) should be made available to the public, and if so, what the role of self-testing should be.

Background/Current Information

- Currently, SARS-CoV-2 Ag-RDTs performed by trained health care workers are used as an alternative to polymerase chain reaction (PCR) testing. The reliance on health care workers limits access to SARS-CoV-2 diagnostic tools, particularly Ag-RDTs, and increases the cost of testing.
- More than 100 countries are supportive of SARS-CoV-2 self-testing, and already have or are in the process of implementing policies in an effort to reduce barriers to testing, empowering individuals to better manage their potential SARS-CoV-2 infection-related symptoms.¹
- The World Health Organization (WHO) is currently reviewing the available evidence on self-testing, in order to develop global guidance.¹
- Numerous products are available for SARS-CoV-2 self-testing.
- As South Africa moves from a containment to a mitigation approach to COVID-19, strategies for diagnosing SARS-CoV-2 infection need to be reviewed.

Evidence review

- Ag-RDTs using lateral flow assays are easy to use, and results can be provided in less than 20 minutes.
- While Ag-RDTs are less sensitive than PCR tests, a positive result suggests the shedding of infectious virus, *i.e.* Ag-RDT negative individuals are less likely to transmit virus.²
- Pre-test probability of infection must be considered when interpreting Ag-RDT results. In a setting of high pre-test probability (e.g. during an epidemic wave or in an exposed, symptomatic individual), a positive Ag-RDT result is likely to indicate infection. However, a single negative Ag-RDT may need to be confirmed with a PCR test or another Ag-RDT in order to exclude a false negative result. Conversely, during periods of low prevalence (e.g. <5% positivity rates), a negative Ag-RDT result is highly predictive of the absence of infection.³
- The greatest utility for Ag-RDTs is during the first 5-7 days of symptoms when the viral load is highest. In asymptomatic individuals, the pre-test probability is low (especially during periods of low prevalence) and testing with Ag-RDTs in this setting should ideally be limited to contacts of confirmed/probable cases or at-risk health care workers, particularly those working in long term care facilities.³

- Self-testing refers to individuals collecting their own specimens from the nose/throat (nose swab, throat swab, saliva), and conducting the test and interpreting the results themselves.
- A number of international studies have shown Ag-RDT self-testing to be acceptable to participants who were able to perform and interpret the tests with adequate sensitivity and specificity.^{4, 5, 6, 7}
- Many countries have implemented self-testing to increase identification of cases to assist with reduction in restrictions, opening up of schools and businesses, and controlling local outbreaks.⁸
- Ag-RDT self-testing allows individuals to obtain a very quick result, which supports the early detection of infectious cases and can reduce community transmission.⁹
- However, inevitably, self-testing will lead to under-reporting of infections, and the reduction in PCR testing will limit the availability of samples for genomic surveillance.^{2, 3}

Recommendations

- Ag-RDT self-testing should be made available to those that wish to make use of this testing option. This can be done through appropriate distribution facilities including pharmacies, health care facilities, workplaces, and by trained health care workers.
- Ag-RDT self-testing in no way replaces existing test modalities, but is meant to complement existing strategies, providing an additional option for people to test and make risk-based decisions that may affect their health, and the health of their families and communities. Anyone uncertain of their self-test result, or desiring alternative professional testing services, should be able to access other available testing options.
- Self-testing can be used:
 - to empower individuals to manage their own health, aiding decision making around accessing health care and isolating to reduce risk to others;
 - to improve access to antivirals that need to be prescribed within a relatively short time frame (e.g. molnupiravir should be administered within 5 days of symptom onset);
 - to manage outbreak situations;
 - for surveillance in settings such as chronic care facilities, the workplace or tertiary education facilities.
- Ag-RDT self-testing, as with any testing, should always be voluntary and never mandatory or coercive. Ag-RDT self-testing, regardless of test results, must always be free from stigma and discrimination.
- Self-testing should not be used for purposes of travel certification.
- Ag-RDTs considered for self-testing should have South African Health Products Regulatory Authority (SAHPRA) approval for the indicated use, and be accompanied by appropriate information resources.
- In order to address concerns about equitable access to affordable Ag-RDTs, the Department of Health could consider making self-testing kits available at government clinics for those that wish to utilise this test option. This may be especially useful in under-resourced areas, or during periods of increased incidence to aid in reducing transmission.
- Those providing and/or distributing Ag-RDTs for self-testing should be adequately trained to provide all the necessary information on their use.
- Sufficient information and clear validated instructions for use must be provided with the Ag-RDT to assist the individual with performing the test, understanding the result and the actions that should be taken following a positive/negative result. The implications of false negative results must be clearly highlighted.
- Information regarding Ag-RDTs should be included in the packaging and modelled on other

successful self-tests, with links to appropriate information websites and the Department of Health COVID-19 helpline.

- Ag-RDT results should be interpreted according to the national testing algorithms.
- Individuals using Ag-RDT self-testing should be encouraged to report all self-test results through the National Health Laboratory Service (NHLS) rapid test reporting portal (<https://csa.nhls.ac.za/>).
- Post-marketing surveillance is essential in order to detect problems with Ag-RDT self-testing kits.
- There must be mechanisms in place to rapidly remove problematic kits or defective batches if tests from the market, as for other SAHPRA-approved medical devices.

Rationale for recommendations

- Ag-RDT self-testing has the potential to increase access to testing, if equitably accessible to all who wish to use this option.
- Ag-RDTs are adequate for detecting those patients who are most infectious, allowing adjustments in behaviour to reduce the risk of transmission to others, as well as shortening the time to access appropriate treatment.
- Self-testing can help reduce transmission by allowing people to test regularly and conveniently at home or in specific settings such as the education sector.
- SARS-CoV-2 infection is already under-reported, as the majority of those infected do not test. Increased access to tests should result in increased testing and diagnosis of infections.

Process for Implementation

- SAHPRA to approve Ag-RDT kits for self-testing that meet SAHPRA's quality assurance requirements.
- Specific guidance for the usage and implementation of Ag-RDT self-testing should be developed.
- Availability and purpose of Ag-RDT self-testing kits to be communicated to the public by the Department of Health.
- With the reduction in PCR testing, processes must be implemented to assist with surveillance focusing on sample-acquisition for testing. This can be modelled on programmes already in existence, e.g. Influenza-like Illness Viral Watch.
- Stakeholder and community awareness of, and engagement in adapting, Ag-RDT self-testing is important for successful implementation. As local epidemiology changes, information on Ag-RDT self-testing that is context-specific, correct, clear, concise and age-appropriate should be made available.

Thank you for consideration of this advisory.

Kind regards



PROF KOLEKA MLISANA



PROF MARIAN JACOBS

CO-CHAIRPERSONS: MINISTERIAL ADVISORY COMMITTEE ON COVID-19

DATE:

CC:

- » **Dr SSS Buthelezi (Director-General: Health)**
- » **Dr N Crisp (Deputy Director-General: National Health Insurance)**

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