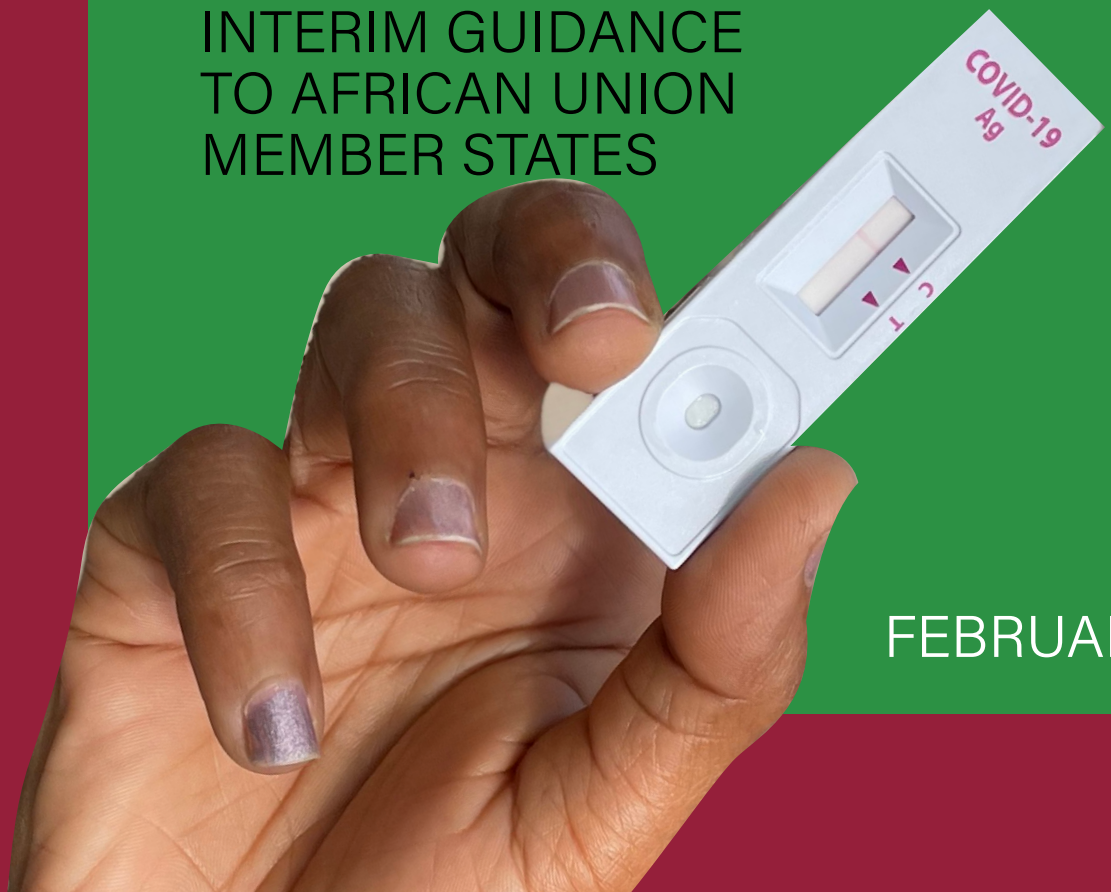
African Union

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

COVID-19 RAPID ANTIGEN SELF-TESTING

INTERIM GUIDANCE TO AFRICAN UNION MEMBER STATES



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EXECUTIVE SUMMARY

Since the first case of COVID-19 was reported in Africa in February 2020, testing to identify individuals infected with SARS-COV-2, the virus that causes COVID-19, has been a cornerstone in controlling the spread of the disease. However, by the end of January 2022, over 94 million tests had been performed across all 55 African Union (AU) Member States with 9 tests performed per confirmed case. This is lower than the WHO recommended testing target of approximately 10—30 tests per confirmed case as the benchmark for adequate testing to control the spread of COVID-19. To counteract these gaps, the Africa CDC and partners have recommended the introduction, adoption and implementation of a COVID-19 rapid antigen self-testing to complement the existing facility-based testing protocols and improve access to SARS-CoV-2 diagnostic testing. The Africa CDC in collaboration with partners developed this interim guidance to provide strategic technical guidance to AU Member States and partners engaged in the COVID-19 response on the introduction and rollout of **SARS-CoV-2 Antigen** self-testing.

This guidance addresses rationale, risk-based scenarios, practical considerations prior to adoption of the self-testing products, quality assurance, safety and ethical considerations, and data management considerations for COVID-19 self-testing.

The Africa CDC recommends the use of rapid antigen self-testing within two key scenarios. The first includes testing for case identification within scenarios with a high risk of infection, including symptomatic cases and contacts of a confirmed case. The second scenario involves general screening within scenarios of low or unknown risk exposure allowing for self-care such as before gatherings with at-risk individuals and prior to participation in events involving members of different households. Within these scenarios, a positive test result indicates likelihood of current infection, while a negative test result indicates a lower risk of active infection, though it does not rule out infection altogether. All positive cases should be managed following the national COVID-19 management protocol of Member States .

Distribution pathways for self-testing can include private sector distribution through pharmacies and private facilities to allow for self-care. Countries should also consider public sector deployment through secondary distribution of self-tests to confirm cases for further distribution amongst household contacts, and, where access would be improved, through distribution to symptomatic individuals and high-risk populations attending health facilities.

Implementation of self-testing requires a comprehensive approach, including the use of only **quality assured products and not using professional use tests for self-testing, ensuring the usability of tests**, and managing the pricing to ensure broader access. At a system level, quality assurance procedures should be put in place and data management solutions should be offered to users for easy reporting of results, when feasible and required. While data visibility may, in the short term, remain a limitation of self-testing implementation, increased testing access has the potential to drive overall test demand and mitigate transmission.

This COVID-19 rapid antigen self-testing interim guidance is recommended for all agencies engaged in the COVID-19 response in AU Member States. As this remains a rapidly evolving area, future guidance, including WHO guidelines and Africa CDC updates, will continue to inform this space. Africa CDC and its partners look forward to supporting the implementation of the guidance provided herein to consolidate efforts to enhance COVID-19 pandemic responses on the African continent and the global community at large.

1. BACKGROUND

1.1. COVID-19 Situation in Africa

As of January 27, 2022, more than 94 million tests (PCR and antigen) have been conducted and more than 10.7 million cases of COVID-19 have been detected in all 55 African Union (AU) Member States, which represents 3% of all cases globally. The COVID-19 positivity rate and the test per case ratio in the general population are the two important parameters for tracking the evolution of the SARS-CoV-2 pandemic. These two metrics together are more informative in understanding the epidemic, rather than being used individually. According to WHO, a positivity rate of <5% within the last two weeks is an indicator that the epidemic is under control in a particular setting. The "test per case" ratio measures the scale of testing relative to the extent of the pandemic, which is simply the inverse of the positivity rate. WHO suggests approximately 10–30 tests per confirmed case as a benchmark for adequate testing. However, Africa's COVID-19 positivity rate and test-per-case ratio were 11.3% and 9, respectively, as of January 27, 2022, well below the WHO targets. This is due to weak surveillance systems and inadequate access and uptake of COVID-19 testing in Member States despite ongoing efforts such as introduction of COVID-19 antigen rapid diagnostics tests (Ag RDTs) at health facilities. To bridge this gap, the Africa Centres for Disease Control and Prevention (Africa CDC) has developed this interim guidance to guide AU Members to adopt and implement new diagnostic innovations for COVID-19 self-testing to scale up access to testing services.

1.2. COVID-19 Rapid Antigen Self-testing

By definition, self-testing is 'a process by which a person collects his or her own specimen using a simple device, performs a diagnostic test and interprets the results usually in a setting, and time of their choice.' In the context of COVID-19 self-testing, this process involves the use of approved *in vitro* SARS-COV-2 rapid antigen kits and devices by an individual to privately collect their own specimen and performs a COVID-19 antigen rapid diagnostic test and interpret their test results as per the manufacturers' instructions.

The WHO defines self-care as "the ability of individuals, families, and communities to promote health, prevent diseases, maintain health, and to cope with illness and disability with or without the support of a healthcare provider." Self-care as a whole can improve equitable access to essential health services, increase individual's engagement with their healthcare, and increase the adoption and use of preventative services. Self-testing, as a self-care approach, has become a standard strategy in the diagnosis and management of other clinical and physiological conditions such as detection of pregnancy in women, and screening and monitoring diabetes, as well as in infectious diseases like HIV/AIDS and hepatitis C virus. Among the benefits of self-testing is the capability to provide testing that enables confidential and convenient access to services that provide a same-day result, often within 15–30 minutes. Such benefits make self-testing appealing to many users across different contexts and settings, including those who may not otherwise seek testing and those at high ongoing risk who may benefit from more frequent testing. Evidence for self-testing across other diseases, when compared to standard testing options, shows that self-testing increases uptake and frequency of testing, is highly acceptable, safe and accurate, and that those who test positive will follow linkages to onward services.

1.3. Rationale of COVID-19 Rapid Antigen Self-testing

Since the start of the pandemic, testing for COVID-19 on the African continent has been largely confined to health facility settings and performed by professional healthcare workers (HCWs) resulting in limited access to COVID-19 testing services. Facility-based testing is limited in that this approach is available to only those who can access health facilities, increases burden on HCWs, delays diagnosis from suspected onset of COVID-19 symptoms, increases travel costs incurred to reach centralized testing, and risks further exposure as people gather at testing facilities, among others. These substantial gaps and inequalities in testing access and uptake hinder the success and maximum benefit of testing services in the response to the pandemic.

Only 20% of AU Member States have recorded positivity rates of <5%, with just 32% of countries have achieved the recommended WHO test per case ratio target, as of January 27, 2022, suggesting the need to increase testing, particularly access to testing, across the region. Multiple challenges remain to scale-up testing to a level that can effectively serve adequate testing volume in response to the COVID-19 pandemic. Africa CDC and its partners recommend that AU Members States introduce and implement COVID-19 rapid antigen self-testing to complement existing COVID-19 testing services and initiatives, and increase community access to COVID-19 testing.

It is critical to note that COVID-19 rapid antigen self-testing is an additional approach that can complement but does not fully replace existing health facility-based testing by professionals such as with molecular tests (i.e. RT-PCR) or Ag-RDTs.

1.4. Benefits and Potential Limitations to COVID Self-testing

In the context of COVID-19, there are benefits and limitations to both the individual and broader health system to consider prior to introducing self-testing.

Benefits:

- Convenience of testing in any setting including one's own home contributing to greater access to and uptake of COVID-19 testing services
- Reduced risk of transmission associated with traveling to see a HCW or attend a testing clinic, or prior to entering specific settings where transmission may occur
- May allow for more frequent testing among high-risk populations
- Possible decongestion of high volume and busy testing sites
- More timely diagnosis and linkage to recommended follow-on services advised by national guidelines, e.g. confirmatory testing, self-isolation, treatment, prevention and risk reduction, including communication to contacts, resulting in subsequent reduction in transmission and timely engagement in care for those who may develop more severe forms of COVID-19
- Self-testing can achieve comparable performance, when used correctly, compared with Ag-RDTs used by professional testers
- Faster care for those who may progress to severe forms of COVID-19
- Cost savings to health systems, from reduction of equipment, infrastructure and personnel time needed as well as additional savings to patients, such as reduced travel time and costs of accessing testing services and less direct cost to consumers

Limitations

- Like with professional-use Ag-RDTs, sensitivity can be variable and lower when compared to RT-PCR assays, particularly during early stages of infections
- Management of the testing process is left to the individual which could result in sub-optimal sample collection and incorrect testing and result interpretation. Anyone uncertain of their self-test result should be encouraged to access existing professional testing services
- Overall performance will vary based on epidemiology. Where prevalence is high and there is active transmission, positive predictive value (PPV) will be high and where prevalence is low and transmission is declining PPV will be lower
- False-positive results may lead to unnecessary self-isolation
- False-negative results may contribute to increased transmission

- Lack of immediate professional support following the test result
- Potential lack of price control in the private sector leading to barriers to access
- Required self-reporting of results makes it difficult to ensure reporting by users, which may impact routine surveillance efforts

Despite the limitations listed above, introduction of self-testing has proven beneficial in increasing access to and uptake of testing for other infectious diseases and can be an important tool to control the spread of the pandemic.

1.5. Purpose of this COVID-19 Self-testing Guidance

The purpose of this COVID-19 self-testing guidance is to provide:

i. regulatory guidance to national regulatory bodies of AU Member States for effective and efficient implementation of COVID-19 self-testing;
ii. strategic technical guidance on the effective and efficient rollout, scale-up and utilization of COVID-19 self-testing to increase community access to COVID-19 testing.

This guidance targets all stakeholders supporting the COVID-19 response in AU Member States including Ministries of Health and other Government agencies, funding agencies, and implementing partners, as well as end-users of self-testing products, among others.

2. USE CASE SCENARIOS FOR COVID-19 SELF-TESTING

2.1. When to Test, and Distribute COVID-19 Rapid Antigen Self-Tests

COVID-19 rapid antigen self-testing should be offered and available for self-assessment as part of the self-care agenda and is therefore considered for use in scenarios where there is a high-risk or high likelihood of infection as well as in scenarios with unknown or low-risk exposure (Fig. 1).

2.1.1. Case identification within scenarios of High Risk or High Likelihood of Infection

Individuals with a high risk or high likelihood of infection may use a COVID-19 rapid antigen self-test to rapidly diagnose infection. Priority scenarios benefiting from self-testing for diagnosis include:

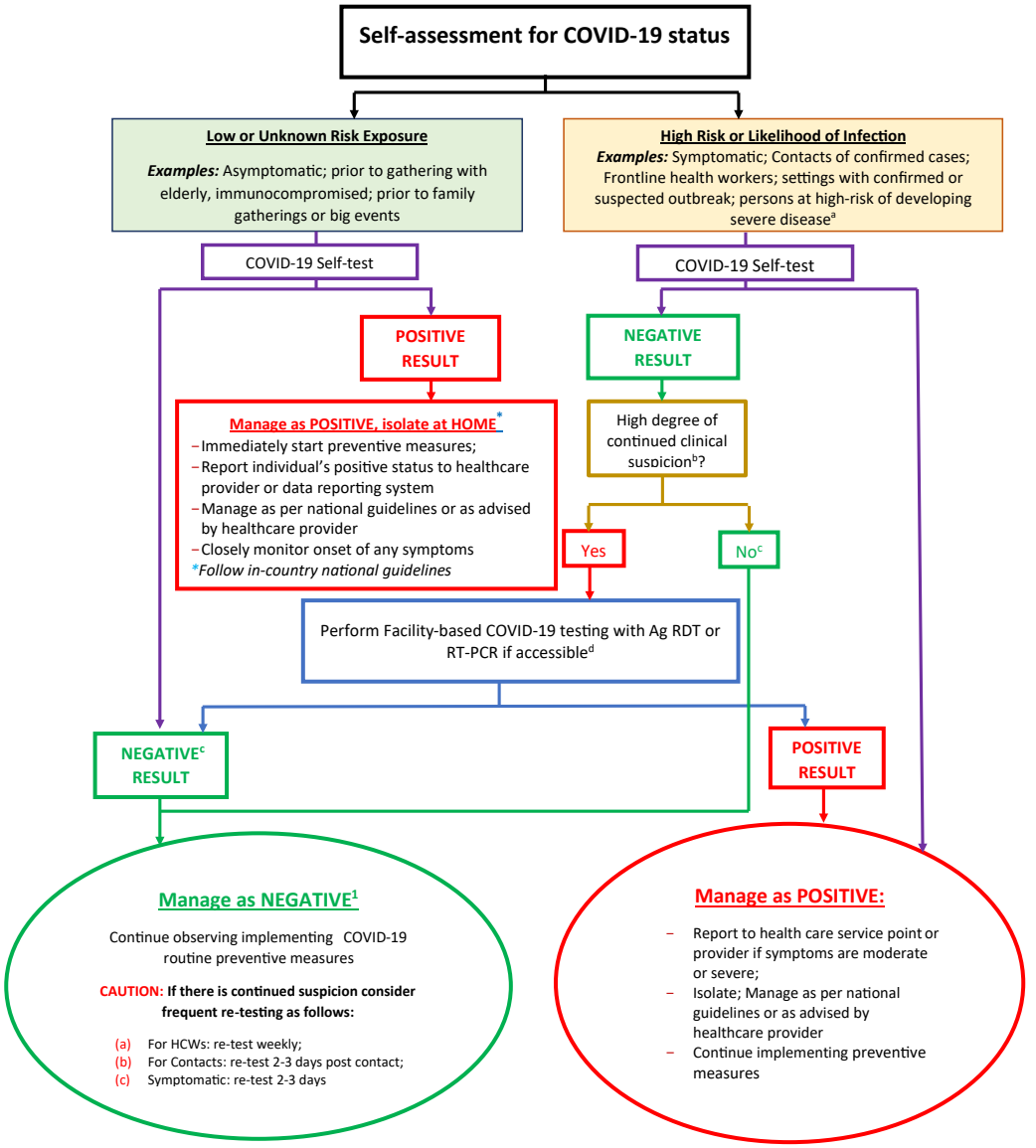
- Individuals with early symptoms and signs of COVID-19
- Contacts of confirmed cases (symptomatic and asymptomatic) within 5 days of assumed exposure
- Among frontline healthcare workers and essential workers (symptomatic and asymptomatic)
- Within settings of confirmed or suspected outbreaks (particularly for the elderly, people with co-morbidities, and populations in closed settings such as prisons, care homes, etc)
- Among individuals at high risk of developing severe disease and their household contacts to ensure faster access to treatment and case management

2.1.2. Testing within Scenarios of Low or Unknown Risk Exposure

Individuals without symptoms or with low or unknown risk exposure may use a COVID-19 rapid antigen self-test as a self-assessment or screening tool to determine their potential risk of spreading the virus. This may be especially important in the following scenarios:

- Before gatherings with older individuals, those who are immunocompromised, individuals at risk of severe disease, and unvaccinated individuals
- Prior to participation in events involving members of different households
- Prior to close interactions with family members, workmates, or groups across sectional ages

Figure 1. Use case scenarios for COVID-19 rapid antigen self-testing



[a] *Examples of persons at high-risk of developing severe disease: immunocompromised individuals, elderly, persons with comorbidities, etc*
[b] *Clinical suspicion, can for example be absence of another obvious etiology, an epidemiological link, or suggestive clinical finding, e.g typical radiological signs (WHO)*
[c] *For patients with moderate or severe symptoms, work up all cases for other signs of illnesses to rule out any other possible cases of the sickness*
[d] *If Facility-based COVID-19 testing with Ag RDT or RT-PCR Is not accessible, repeat COVID-19 Ag self-test after 2-3 days.*

2.2. Result Interpretation of COVID-19 Self-test Results:

Self-testing results will have different interpretation needs depending on the self-testing scenario. Simplified communication modalities should be available for end-users to accurately interpret results.

In general, a **positive test** result indicates a likelihood of current infection, which should be followed by isolation and informing all close contacts. On the other hand, a **negative test** result may indicate a lower risk of active infection although infection is not ruled out. Infection may be more likely among populations within the high risk of infection scenario and repeat testing may increase confidence in the case of negative results. Individuals with moderate to severe infection should seek care to assess other potential causes for symptoms.

2.3. Consideration for Frequency of Testing

Individuals within the high-risk of infection group should consider retesting after an initial negative self-test result. For contacts and symptomatic individuals, individuals should continue to isolate, if possible, follow strict infection prevention measures and perform either a facility-based COVID-19 Ag-RDT or RT-PCR test if accessible, or use a self-test for retesting.

Retesting frequencies can be considered as follows:

- Healthcare workers should consider retesting weekly, especially during periods of community transmission
- Contacts of confirmed cases should test within 2–3 days of the first contact and repeated every 2-3 days until 14 days post initial exposure
- Symptomatic individuals should test 2–3 days after first symptom onset

Note this is general guidance: No test will eliminate the risk of a false positive or false negative result and result interpretation decisions should be made based on the estimated COVID-19 prevalence and test performance. Each AU Member State is encouraged to develop its testing guide targeting both end-users and healthcare professionals so that they meet the in-country local context in relation to other COVID-19 response interventions.

2.4. Distribution of COVID-19 Rapid Antigen Self-testing Use Case Scenarios

Like other common self-tests, COVID-19 self-testing is a tool for self-care and can be offered across multiple populations in both public and private sectors, and in settings where professional antigen RDTs are currently being deployed as provided in the Africa CDC interim Guidance on the use of rapid antigen tests for COVID-19 Response. These tests allow for further decentralization of testing and can be delivered in facilities, communities, workplaces, homes and the private sector.

Private Sector

Individual Self Care: Engagement with the private sector to offer self-tests can rapidly increase access to individuals who have an identified need to test, as discussed in Section 2 above. Equipping pharmacies with regulated COVID-19 self-testing products for purchase can cultivate broader self-testing knowledge and demand. Within this setting, self-testing distribution volumes can be routinely monitored to estimate demand and inform procurement needs. Accessible pricing in these settings should be a priority.

Public Sector

Household contacts of confirmed cases: Self-tests can be given to all confirmed cases to distribute to household contacts for timely identification of transmission and to protect those at higher risk of severe disease. Distribution of self-tests to symptomatic individuals and household contacts

of confirmed cases may have the potential to increase testing access while also alleviating the burden on healthcare workers administering professional use Ag-RDTs. It is important to promote preventive measures during these processes, for example, provision of masks to the confirmed cases to minimize risks of transmission to their household members. All the other recommended in-country COVID-19 preventive measures should be observed.

Dependent on country contexts, countries may consider distribution pathways, including:

Facilities within identified hotspots: As community hotspots are identified, provision of COVID-19 self-tests to all clients visiting a health facility, regardless of risk of infection, may lead to rapid identification and isolation of new cases. All public sector uses of COVID-19 self-testing will depend on the available supply of COVID-19 self-testing commodities.

Symptomatic individuals at health facilities: Within the public sector, COVID-19 self-testing could be offered as an alternative to professional use Ag-RDTs for all symptomatic individuals upon arrival at the testing site. Provision of self-testing among symptomatic individuals at health facilities can also allow for timely monitoring and reporting of self-testing distribution and outcomes which can inform routine surveillance data and inform local public health responses.

Populations at higher risk: COVID-19 self-testing should be made available to high-risk populations depending on the country context. Such populations include care homes for the elderly, refugee camps, military barracks, and other such settings. As well, some medical conditions and immunosuppression predispose individuals to a higher risk of infection and mortality, and distribution can occur through care touchpoints, like with antiretroviral sites distributing to people living with HIV at routine visits or via community worker channels.

2.5. AU Member State Adaptation

At national level, AU Member States are encouraged to develop and establish in-country specific policies and guidelines for COVID-19 self-testing in line with the local guidance and local dynamics of the pandemic. In-country use cases for COVID-19 self-testing should be defined and measures put in place to ensure all stakeholders adhere to them. Adequate and appropriate information, education and communication materials on COVID-19 self-testing should be made available to communities.

3. KEY CONSIDERATIONS FOR INTRODUCING COVID-19 SELF-TESTING

3.1. Regulatory Considerations

The AU Member States should carefully choose the appropriate test(s) based on intended use and settings while taking into account national, international and regional regulatory considerations on use of new diagnostics for self-testing. COVID-19 self-testing kits that have been assessed through the WHO Emergency Use Listing (EUL), national Emergency Use Authorization (EUA) procedures, and/or those that demonstrated acceptable performance characteristics on independent evaluation using a relatively larger sample size should be prioritized for COVID-19 self-testing. It is also recommended to AU Member States to consider products listed by national regulatory authorities in International Medical Devices Regulators Forum (IMDRF) jurisdictions. The requirements for EUA may vary substantially among countries and are less rigorous than the regulatory approval procedures in non-emergency situations. Member States should avoid engaging in evaluation of self-testing kits as long as performance data is available from credible evaluations performed somewhere else. In such circumstance, countries instead can focus on

verification studies at national reference laboratories, lot testing during procurement and post-market surveillance.

It is important to note that professional use COVID-19 Ag-RDTs should not be sold or used as COVID-19 self-testing kits even though a number of manufacturers produce both professional use and self-test versions of the same test.

3.2. Performance Characteristics and Additional Product Considerations

The current Ag-RDTs target product profile specifies products should achieve at least 80% sensitivity and 97% specificity. Products considered for self-testing should have the same inherent analytical sensitivity and specificity as required for professional use products and achieve good agreement when comparing test performance in the hands of self-testers to professional testers. Like field performance of Ag-RDTs used by professionals, Ag-RDTs used by self-testers may vary. Products for self-testing will need to be robust and have high usability.

However, observed performance in the hands of lay-operators may likely be slightly lower. As seen in other self-test protocols such as HIV self-testing, adherence of users to appropriate, clear and concise instructions for the use of self-test kits can minimize errors and maximize the performance of self-testing products. Printed instructions, job aids and pictorial illustrations provided along with the self-test kits, as well as videos, peer support, and hotlines are essential to support correct use of the products and ensure adequate performance of the assay.

Additional factors beyond performance should be considered when selecting tests, including user experience, literacy levels and distribution and supply networks, affordability, range of validated sample types, and anticipated product acceptability. In particular, storage conditions and shelf-life of the products should be taken into careful consideration, as variability in temperature and fluctuations in demand may impact product accuracy and utility.

3.3. Usability

COVID-19 self-tests may vary in their requirements for specimen type, number of processing steps, required reagents and consumables, and interpretation of results, which may influence the usability of the self-test among individuals. Therefore, it is recommended to consider available data on usability of the tests when selecting products for introduction. Where desired, an ease-of-use assessment may be utilized and a recommended checklist of COVID-19 self-test kit contents and capabilities annexed for reference and may need to be adapted for products of national interest (Annex II).

Self-test kits should be supplied with easy-to-use instructions for sample collection, testing and result interpretation as well as information on storage and operational temperatures. Some tests may also come with video instructions for use while other tests are sold with a requirement for proctored or supervised testing. It is therefore recommended that AU Member States organize the necessary communication modalities for users to engage with support for testing and results interpretation. These may include hotlines, online tutorials, or volunteers for added support as well as mass media communication channels to broadly spread information.

3.4. Supply and Logistics

The number of COVID-19 self-tests has massively expanded over the past year, with many new companies entering the market. Considerations should be given to a supplier's distribution and product support capacity, especially in low and middle-income countries. Accurate quantification and demand forecasting are critical to ensure ample and accessible supply of self-tests while mitigating risk of expiration. Supply chain management systems should be expanded to include self-tests, where utilized, to minimize risk of stock-outs.

3.5. Regulation of Pricing

The cost of tests will vary according to the test and the volume to be purchased. In general, COVID-19 self-tests should be made affordable to ensure equitable access. Where possible and as test kits become available for procurement through pooled procurement agencies, global reference pricing will be made publicly available.

The cost of transportation, import tariffs, storage, and post-purchase quality control testing activities required to support quality implementation of self-tests must also be considered. Distributor mark-ups should be critically evaluated to ensure fair pricing and the accessibility of global reference prices. Where possible, direct procurement or procurement through pooled procurement agencies should be leveraged to minimize cost increases.

Pricing offered through the private sector should be monitored to ensure equitable access to testing.

4. QUALITY ASSURANCE

In order to optimally gain from the benefit of self-testing, it is recognized that deliberate efforts must be made to ensure quality test results. The three core components of quality assurance as defined by the Quality Assurance Framework for SARS-CoV-2 Antigen Rapid Testing for COVID-19 diagnosis should be implemented by AU Member States and all stakeholders supporting and implementing this intervention.

AU Member States should plan and implement follow-up field supervision of private and public sector COVID-19 self-testing distribution points to determine if the practices for COVID-19 self-testing are in-line with established policies and guidelines. Supervision visits and other post market assessments can also be used to monitor the appropriate distribution and use of the kits. This may include determining if their validity in the field meets the expected performance characteristics, detecting defects in the products that negatively affect performance, appropriate distribution of kits, and ensuring correct functioning, reading and interpretation of internal quality control results by individuals performing the COVID-19 self-test. Data collected on quality monitoring should be plugged back into the national COVID-19 response programme.

5. SAFETY AND ETHICAL CONSIDERATIONS

5.1. Safety Considerations in COVID-19 Self-testing

Safety considerations must be addressed when introducing, adopting and implementing COVID-19 self-testing products. These include product quality issues, practices of handling sample collection and the test by the users when performing self-testing, management of test results, and waste management and disposal of used kits by the users.

Deliberate sensitization campaigns and education messaging may be necessary and will likely need to be product-specific, addressing topics including safe sample collection and handling, correct test administration, and safe waste disposal. Key messages should address the following:

- Guidance that users must read and adhere to manufacturer's instructions and illustrations for proper use of the products
- Use of the kits must be supervised by an individual who is competent to perform the test where users may have physical impairments like blindness, or inability to read and comprehend the manufacturer's instructions like the elderly and those below the age of consent
- Users must not ingest any of the product's contents and must ensure that these products are kept out of the reach of children

- Keen emphasis must be put on the correct reading and interpretation of the test results

Clear and concise safety instructions should be included with self-test kit distribution and purchase.

5.2. Ethical considerations in COVID-19 self-testing

Like any other healthcare service, AU Member States should develop and/or where applicable adopt the regulatory policies and ethics guidelines that will protect users and promoters of COVID-19 self-testing technologies. The guidelines must recognize the importance of human rights, and ensuring no coercive of mandatory COVID-19 self-testing.

Important considerations include:

- Users should not be coerced to conduct COVID-19 self-testing
- Self-testing must be voluntary unless otherwise legally required (by lawful means)
- There should be no bias for or against access to COVID-19 self-testing services
- Provide means through which misuse and abuse of COVID-19 self-testing services can be communicated by users and beneficiaries
- After individuals perform COVID-19 self-testing, there must be clearly defined appropriate action(s) provided for those with both negative and positive results according to national guidelines
- Address cost and other barriers for self-testing to ensure equitable access

Ultimately, all relevant data and information pertaining to COVID-19 self-testing kits and devices including their limitations and risks must be made readily available to policymakers and users and consumers by the manufacturer's suppliers and distributors of the kits.

6. DATA MANAGEMENT FOR COVID-19 SELF-TESTING

Data from self-testing can be critical to inform decision-making within-households or transmission networks. These data may also provide supplementarily, but not the only data points for informing national or regional disease control. COVID-19 self-testing data is reliant on self-reporting and will depend on individual choice, ease-of-reporting, the stage of pandemic in-country, and country-specific requirements. Individuals who test negative may be less inclined to report their results while those who test positive may primarily report outcome data if they need medical attention from a professional healthcare service point. It is also possible that an individual with a positive test result may not report their result if the result compromises work, income, or travel. Simplifying the reporting needs and mechanisms for the public following self-testing alongside communication on the importance of sharing test results will aid timely reporting for all self-testing users. Of note, variable uptake of testing by selected populations may confound interpretation of trends on testing rate and positivity rate and should be taken into consideration by national programs.

AU Member States are encouraged and guided to develop country-specific data collection tools and applications for easy data collection relevant to the context of the country's COVID-19 response. These tools should be compatible with and integrate testing data into already existing in-country health information management systems. As more digitalized options become available, it is recommended that user-friendly electronic application data collection tools are developed and adopted for users for self-reporting, for example via mobile telephone. To address issues of confidentiality, countries should ensure that the data management systems established be robust enough to maintain the integrity of the data and avert risks of data loss. Data access levels must be defined to prevent unauthorized risks of data alterations and to uphold confidentiality.

Data regarding procurement and distribution volumes within both the public and private sectors can serve as a proximal indicator to determine self-testing reach and potential for increased testing access within the national response.

ANNEXES

Annex I: Glossary of Key Terms

Ag-RDTs	Antigen rapid diagnostic tests are immunoassays used to detect the presence of a pathogen in a patient sample by identifying its proteins. Although not as sensitive as molecular assays, they are more affordable, easier to use, and can give a result in 15-20 minutes. In the context of COVID-19 self-testing, the samples commonly used with AG-RDTs are nasal o oropharyngeal swabs depending on the manufacturers' specifications.
Asymptomatic	This refers to when a person does not have symptoms for a particular clinical condition or disease when the condition or disease is present. In the context of COVID-19 self-testing, asymptomatic means absence of COVID-19 symptoms despite a positive test result
COVID-19	COVID-19 is a disease caused by a highly infectious severe acute respiratory syndrome coronavirus (SARS-CoV-2) which is transmitted when one inhales air contaminated with the virus or when one touches his/her eyes, nose or mouth with hands contaminated with the virus after contact with a contaminated surface(s).
COVID-19 Self-testing	This is a process by which a person collects his or her own specimen from his or her body using a simple device and uses that specimen to perform a COVID-19 diagnostic test and interprets the results.
Emergency Use Authorization (EUA)	This is a regulated process by which a national or international reputable body may allow the use of unapproved medical products in emergency situations to diagnose, treat or prevent very serious or life-threatening clinical conditions particularly in cases where no approved alternatives are available.
Emergency Use Listing (EUL)	This is a WHO risk-based regulatory procedure used for assessing and listing medical products and therapeutics, including in-vitro diagnostic kits, with the objective of ensuring that the medical products are safe, and of acceptable quality and performance before they are released onto the market and distributed to the population for use
Pandemic	A pandemic is an epidemic occurring worldwide, or over a very wide area, crossing international borders and usually affecting a large number of people within a short time
Quality Assurance	Quality assurance in the context of COVID-19 self-testing refers to the collective efforts and processes that are implemented, monitored and evaluated to ensure the quality of test results are accurate and reliable.
Quality control	This refers to the measures incorporated in each COVID-19 self-testing procedure to ascertain and verify that the diagnostic kit and associated reagents and supplies are working properly to produce accurate and reliable COVID-19 test results
Molecular testing	This refers to assays that are used to identify a pathogen in patient samples by detecting and amplifying one or more of its genes. These assays are highly sensitive and specific and are available in laboratory-based or point-of-care formats. There are currently no self-tests based on molecular methods but they can be used to confirm self-testing results.
SARS-COV-2	This is a highly infectious coronavirus strain responsible for causing the ongoing COVID-19 pandemic. The virus is transmitted when one inhales air contaminated with the virus or when one touches his/her eyes, nose, or mouth with hands contaminated with the virus after contact with a contaminated surface(s)
Symptomatic	This refers to when a person has specified characteristic signs and symptoms of a defined disease or clinical condition. In the context of COVID-19, a person who has the WHO-defined signs and symptoms of COVID-19 is said to be symptomatic.

Annex II: COVID-19 Ag-RDT Usability Checklist

- Test is simple to conduct for a layperson, requiring a minimal number of steps
- Test does not require any additional instrumentation or equipment beyond kit contents
- Test utilizes a simple sample collection method, preferably nasal or saliva collection
- Kit manufacturer information is legibly written in a language(s) understood by the users
- Kit includes simple clear step-by-step instructions on how to use the kit to perform the self-test. Pictorial diagrams are highly recommended to minimize errors and maximize the performance
- Kit instructions cover proper protocols to handle and store the test kits before use
- Kit allows for easy reading and interpretation of test results
- Kit instructions should also inform individuals limitations of the test kits and any relevant safety issues including how to safely dispose of the used test kit
- Kit instructions should be user-friendly for a non-health trained individual to interpret

REFERENCES

1. Africa CDC. Quality Assurance Framework for SARS-CoV-2 Antigen Rapid Testing for diagnosis of COVID-19. Africa CDC Quality Assurance Framework for SARS-CoV-2 Antigen Rapid Testing for diagnosis of COVID-19
2. Africa CDC. Interim Guidance on the Use of Rapid Antigen tests for COVID-19 Response. Africa CDC interim Guidance on the use of rapid antigen tests for COVID-19 Response
3. Brümmer, Lukas E., et al. "Accuracy of novel antigen rapid diagnostics for SARS-CoV-2: A living systematic review and meta-analysis." *PLoS medicine* 18.8 (2021): e1003735.
4. Cattelan, Anna Maria, et al. "An integrated strategy for the prevention of SARS-CoV-2 infection in healthcare workers: a prospective observational study." *International journal of environmental research and public health* 17.16 (2020): 5785.
5. Eshun-Wilson, Ingrid, et al. "A Systematic Review and Network Meta-analyses to Assess the Effectiveness of Human Immunodeficiency Virus (HIV) Self-testing Distribution Strategies." *Clinical Infectious Diseases* 73.4 (2021): e1018-e1028.
6. Ferretti, Luca, et al. "Quantifying SARS-CoV-2 transmission suggests epidemic control with digital contact tracing." *Science* 368.6491 (2020): eabb6936.
7. International Medical Device Regulators Forum (IMDRF). https://www.imdrf.org/about
8. Jamil, Muhammad S., et al. "Examining the effects of HIV self-testing compared to standard HIV testing services in the general population: A systematic review and meta-analysis." *EClinicalMedicine* 38 (2021): 100991.
9. Remme, Michelle, et al. "Self-care interventions for sexual and reproductive health and rights: costs, benefits, and financing." *bmj* 365 (2019).
10. Treibel, Thomas A., et al. "COVID-19: PCR screening of asymptomatic health-care workers at London hospital." *The Lancet* 395.10237 (2020): 1608-1610.
11. World Health Organization. *Considerations for school-related public health measures in the context of COVID-19.* WHO-2019-nCoV-Adjusting_PH_measures-Criteria-2020.1-eng.pdf
12. World Health Organization. *WHO audio emergencies coronavirus press conference.* who-audio-emergencies-coronavirus-press-conference-full-30mar2020.pdf
13. World Health Organization. *Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services*. World Health Organization, 2016.
14. World Health Organization. WHO releases first guidelines on hepatitis C virus self-testing. https://www.who.int/news/item/15-07-2021-who-releases-first-guidelines-on-hepatitis-c-virus-self-testing
15. World Health Organization. "WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices." (2017).
16. Witzel, T. Charles, et al. "Comparing the effects of HIV self-testing to standard HIV testing for key populations: a systematic review and meta-analysis." *BMC medicine* 18.1 (2020): 1-13.

COVID-19 RAPID ANTIGEN SELF-TESTING

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