



REVISED COVID-19 Testing Strategy

TRANSITIONING FROM EMERGENCY RESPONSE TO
INTEGRATION INTO ROUTINE HEALTHCARE SERVICES

Guidance to African Union Member States

Second Edition, August, 2022

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Africa Centres for Disease Control and Prevention
(Africa CDC)
Roosevelt Street, Old Airport Area, W21 K19
P. O. Box 3243, Addis Ababa, Ethiopia
Tel: +251 11 551 7700
Email: africacdc@africa-union.org

ACKNOWLEDGMENT

The Africa Centres for Disease Control and Prevention (Africa CDC) acknowledges the enormous contribution received from its Partners during the development of this guidance for integrating COVID-19 testing into routine healthcare services.

In particular, the Africa CDC appreciates the technical inputs provided by the Members of the AFTCOR Laboratory Technical Working Group whose deliberations enriched the guidance to foster integration of COVID-19 testing into routine healthcare services.

In addition, the Africa CDC would like to recognize and acknowledges the individual listed here below for the review and inputs provided during the development of this guidance:

- Abimiku Alash'le (Institute of Human Virology, Nigeria)
- Anafi Mataka (African Society for Laboratory Medicine)
- Anne Von Gottberg (National Institute for Communicable Diseases, South Africa)
- Ashley Kallarakai (Clinton Health Access Initiative)
- Aytenew Ashenafi Eshete (Africa Centres for Disease Control and Prevention)
- Fatim Cham-Jallow (The Global Fund)
- Jane Carter (Amref Health Africa)
- Juliet Bryant (The Global Fund)
- Mah-Sere Keita (African Society for Laboratory Medicine)
- Ndlovu Nqobile (African Society for Laboratory Medicine)
- Osborn Otieno (The Global Fund)
- Owen Demke (Clinton Health Access Initiative)
- Pascale Ondo (African Society for Laboratory Medicine)
- Trevor Peter (Clinton Health Access Initiative)
- Rosanna Peeling (London School of Hygiene & Tropical Medicine)
- Shaukat Khan (Clinton Health Access Initiative)
- Silver Mashate (African Society for Laboratory Medicine)
- Stephanie Salyer (Africa Centres for Disease Control and Prevention)
- Yenew Kebede Tebeje (Africa Centres for Disease Control and Prevention)

EXECUTIVE SUMMARY

Testing to identify people infected with SARS-CoV-2, the virus that causes COVID-19, has been central to the control of the disease. The African Union Commission, through the Africa Centres for Disease Control and Prevention (Africa CDC) and partners, implemented a number of key initiatives to expand COVID-19 testing in Africa including developing guidance on the use of [rapid antigen tests](#), self-testing, and genomics surveillance

During the initial emergency response phase of the COVID-19 pandemic, testing efforts concentrated on identifying individuals infected with SARS-CoV-2 for timely isolation, contact tracing and clinical care to break the chain of transmission and minimize morbidity and mortality. The purpose of this revised testing strategy is to guide AU Member States on the shift from the emergency response phase to the integration of COVID-19 testing and management into routine clinical and public healthcare services. It provides guidance on the provision of COVID-19 testing for clinical purposes and surveillance for public health response, as well as considerations for monitoring and evaluation approaches.

This revised guidance recommends that access to COVID-19 testing is decentralized as far as possible and made available at health facilities, and through the use of self tests to enable access to care and the mitigation of transmission. Testing should be prioritized for high-risk and vulnerable individuals presenting with acute onset of respiratory illness so that those found to be infected can benefit from clinical care and access to COVID-19 therapeutics and vaccines. COVID-19 testing should also be integrated with routine care and diagnosis, including for malaria, HIV, TB, influenza-like illness and other respiratory infections.

Given the global diversity and continued rapid evolution of SARS-CoV-2, countries are encouraged to develop sustainable approaches to monitor trends in SARS-CoV2 transmission. Integrating SARS-CoV-2 testing into existing surveillance systems will be necessary to understand the public health significance of endemic SARS-CoV2, and how it will impact the co-circulation of other endemic acute and chronic respiratory infections. In addition to case-based monitoring systems, innovative alternative population-based approaches to surveillance are encouraged, such as environmental surveillance and systematic seroepidemiological surveillance. These approaches may be particularly useful tools for tracking trends in COVID-19, as they are independent of changes in diagnostic testing practices.

This testing strategy guidance is meant for stakeholders supporting the COVID-19 response including Ministries of Health and other Government agencies, National COVID-19 response task-forces, funding and implementing agencies, public health experts, epidemiologists, front-line professional healthcare service providers including clinicians, nurses, laboratory professionals, community healthcare workers and others.

Africa CDC is aware of the rapidly evolving epidemiological nature of COVID-19 and that changes in control measures may need to be taken to address changes in the nature of the pandemic as these arise and hence this guidance will be updated as needed. The Africa CDC looks forward to successful adoption and implementation of this guidance to augment efforts to transition from emergency to integration of COVID-19 testing into routine healthcare services.

1.0 BACKGROUND AND RATIONALE FOR REVISION

In response to the COVID-19 pandemic, the African Union (AU) rolled out the Partnership to Accelerate COVID-19 Testing (PACT) to scale up testing for COVID-19 in June 2020. This continental initiative helped AU Member States limit COVID-19 transmission while ensuring an increased access to diagnostics and medical supplies, as well as front-line personnel needed to support response at the country level¹.

In between the launch of PACT and the revision of this COVID-19 testing strategy several guidance documents have been launched by the Africa Centres for Disease Control and Prevention (Africa CDC) and partners including guidance on the use of [rapid antigen tests](#)²; self-testing to complement the existing facility-based testing protocols and improve access to SARS-CoV-2 diagnostic testing³; and genomics surveillance to help AU Member States better understand the variants currently circulating⁴. However, recent changes in vigilance with respect to the COVID-19 response in Africa, including a decline in testing, call for a revision of the COVID-19 testing strategy for Africa.

Additionally, new innovation in diagnostic tools, treatment and surveillance including prevention approaches have emerged and have contributed to the clinical care needs of SARS-CoV2 infected individuals. These include the introduction of multi-disease testing technologies and new SARS-CoV-2 antiviral therapies that can significantly reduce hospitalization time, severe disease, and mortality in high risk patients if administered early⁵. Thus, early diagnosis and quick access to therapy is necessary for treatment success.

As the virus establishes endemic transmission, it will be important to sustain capacities for monitoring and tracking trends in SARS-CoV-2 transmission. Incorporating SARS-CoV-2 testing within routine health services and existing surveillance such as Influenza like illness (ILI) /Severe Acute Respiratory Infection (SARI) sentinel surveillance and Integrated Disease Surveillance and Response (IDSR) is needed to make surveillance sustainable. We further need to consider continuing scaling up of the use of Ag-RDT, including self-testing, as well as establishing novel methods of surveillance with consideration for environmental or waste-water surveillance.

1.3 Purpose of this COVID-19 testing strategy

The purpose of the revised testing strategy is to guide AU Member States with a shift from emergency response to routine public health monitoring of COVID-19 on the African continent.

The strategy provides guidance on:

- i. Provision of SARS-CoV-2 testing for clinical purposes, including enabling COVID-19 testing and treatment to be integrated into routine health services for efficient delivery.
- ii. Integrating SARS-CoV-2 testing into existing and new surveillance systems to monitor ongoing COVID-19 transmission and identify potential surges and shifts in disease trends in order to inform timely decision-making and guide the effective implementation of public health and social measures (PHSM).

1 <https://africacdc.org/news-item/african-union-rolls-out-partnership-to-accelerate-covid-19-testing/>

2 <https://africacdc.org/news-item/new-guidance-to-expand-rapid-antigen-testing-for-covid-19-response-in-Africa-released/>

3 <https://africacdc.org/download/interim-guidance-on-covid-19-rapid-antigen-selftesting-to-african-union-member-states/>

4 <https://africacdc.org/download/interim-operational-guidance-on-sars-cov-2-genomic-surveillance-in-africa-an-updated-guide/>

Target audience

This revised COVID-19 testing strategy is meant for:

- Stakeholders supporting the COVID-19 response in Member States including Ministries of Health and other government agencies, national COVID-19 response task-forces and technical working groups (TWGs), funding agencies and implementing partners, public health experts, and epidemiologists
- Professional healthcare service providers including clinicians, nurses, laboratory professionals, and others
- Authorized community healthcare workers (CHWs) and where relevant community level leaders

Note: It is important to note that the high-level guidance provided in this strategy may be operationalized and implemented in combination with other relevant detailed technical guidance.

2.0 COVID-19 TESTING STRATEGIES FOR CLINICAL PURPOSES

2.1 Prioritized COVID-19 testing for clinical management

COVID-19 testing should be made easily accessible for the following high risk and vulnerable patients with the goal of reducing severe illness, hospitalization, morbidity and mortality:

- Patients presenting for clinical care with symptoms suggestive of SARS-CoV-2 infection
- Elderly patients (>65 years old)
- Immunosuppressed/Immunocompromised patients
- Patients with chronic diseases and underlying conditions such as hypertension, diabetes among others

High-risk patients presenting with acute onset of respiratory illness at health facilities should be prioritized for COVID-19 testing (Table 1). Testing should also be offered to high-risk household contacts of cases, such as the elderly, persons with co-morbidities like hypertension, diabetes, and other chronic clinical conditions to ensure they receive rapid care if they are to become infected. Lack of vaccination in these populations may further increase their risk for severe COVID-19. Patients in the general population who meet the COVID-19 case definition may also be offered testing, especially during a surge.

It is essential that all individuals who test COVID-19 positive should receive subsequent care based on the country's case management guidelines. This can include drug therapy and medical oxygen if needed.

2.2 Coverage and Accessibility to COVID-19 Testing

Diagnostic testing for SARS-CoV-2 remains a critical component for the early identification and clinical management of individuals with COVID-19. Despite the current reduction in the number of COVID-19 cases, access to COVID-19 testing should be widely available at all health facilities together with other essential diagnostics. This includes the lowest levels of public health facility to the highest tiers at regional and national levels, and within private healthcare facilities at affordable cost.

Improved access to testing will allow for faster linkage to care and treatment and contribute to enhanced public health surveillance for the management of emergence of new variants and surges. A number of quality-assured antigen rapid antigen diagnostic tests, including self tests, are now available and should be made broadly accessible within health facilities and for testing by high risk patients. This is aimed at ensuring quick access to testing alongside strong referral pathways to enable timely linkage to clinical treatment within the first 5 days of symptom onset. Within the specimen referral pathways, it is recommended to incorporate necessary mechanisms to facilitate processes to send specimens for sequencing based on the national sampling strategy.

2.3 Integration of COVID-19 testing into routine healthcare systems

COVID-19 screening and testing should be integrated into the routine healthcare services including out-patient departments, in-patients wards and in special clinics for high risk individuals. COVID-19 screening and testing should be integrated into routine care for TB, influenza and respiratory diseases, malaria, HIV, and other febrile illness or related symptoms.⁴ Specific guidance is outlined below and in Table 1:

- HIV patients are at higher risk of mortality and morbidity following COVID-19 infection⁵. As patients present at an ART clinic, they should routinely be screened for COVID-19 symptoms. If they meet the clinical criteria for COVID-19 or are contacts of confirmed cases, particularly those with advanced HIV disease or co-morbidities, then COVID-19 rapid antigen testing should be provided followed by therapy if positive. Support should be provided to people living with HIV to continue taking antiretroviral therapy and adapting services, including prevention and linkage to treatment, to make this easier and less risky during the COVID-19 response. This includes access to self tests for HIV patients to allow them to test themselves at home if they develop symptoms or suspect exposure, without the need to risk exposure or delay in access to testing within the healthcare system. A positive self test is considered diagnostic and should enable access to COVID-19 therapeutics.
- There is an overlap of symptoms across TB and other respiratory diseases with COVID-19 disease, and this provides an opportunity for the integrated clinical evaluation of both diseases within populations presenting for respiratory illness. If patients meet the clinical criteria for COVID-19 testing, then COVID-19 rapid antigen testing should be provided. In addition there are opportunities for bidirectional TB-COVID-19 testing to improve case finding for both diseases^{6,7}.
- Early symptoms of SARS-CoV-2 infection such as myalgia, fever, and fatigue overlap with symptoms of malaria and other non-malaria febrile illnesses leading to challenges in early clinical diagnosis. In malaria-endemic countries, all suspected malaria cases should receive parasitological confirmation of malaria by quality-assured microscopy or rapid antigen tests prior to administration of antimalarial drugs⁸. Due to availability of rapid tests, malaria testing has been decentralized to lower tier health facilities and at the community level in most member states. It is important to also ensure the availability of SARS-CoV-2 rapid tests and therapeutics at these facilities.

4 <https://apps.who.int/iris/bitstream/handle/10665/341126/WHO-2019-nCoV-TB-care-20211-eng.pdf>

5 <https://pubmed.ncbi.nlm.nih.gov/35561704/>

6 Briefing Note. Testing for Both Tuberculosis and SARS-CoV-2. Geneva, the Global Fund, 2021. https://www.theglobalfund.org/media/11438/covid19_tb-testing_briefingnote_en.pdf.

7 *WHO Information Note: COVID-19 Considerations for Tuberculosis (TB) Care*. Geneva, World Health Organization, 2021. <https://apps.who.int/iris/bitstream/handle/10665/341126/WHO-2019-nCoV-TB-care-20211-eng.pdf>

8 WHO consolidated guidelines for malaria <https://www.who.int/teams/global-malaria-programme/guidelines-for-malaria>
IMCI : https://cdn.who.int/media/docs/default-source/mca-documents/child/imci-integrated-management-of-childhood-illness/imci-in-service-training/imci-chart-booklet.pdf?sfvrsn=f63af425_1

2.3.1 Strategies for integration of COVID-19 testing into routine healthcare services

To foster pragmatic integration COVID-19 testing and management into routine healthcare services and alongside existing HIV, TB and malaria programs, the following strategies are recommended to AU Member States:

- All health facilities from the lowest level and above should be resourced with necessary diagnostics, competent personnel and adequate supplies to provide COVID-19 testing services and other priority conditions. All healthcare service providers should be trained to recognize COVID-19 symptoms among patients who present at health facilities for routine services
- Testing policy updates should allow for seamless integration of testing for COVID-19 within HIV, TB and malaria programmes and febrile case management, together with the development of relevant implementation tools.
- Establishment of clear coordination mechanisms between different disease programmes and COVID-19 control programmes, and regular review of the integration of policies and guidelines.

Table 1: Guidance on integration of COVID-19 testing services

Clinical settings for integrated COVID-19 testing services	Guidance on individuals to be prioritized for COVID-19 screening and testing
<p>Routine healthcare services</p>	<p>Prioritized individuals</p> <ul style="list-style-type: none"> ■ Vulnerable and high-risk individuals such as the elderly, people with immune-deficiencies and people living with chronic diseases presenting at health facilities with acute onset of respiratory illness ■ Individuals with high-risk of progression to severe COVID-19 disease, including those with co-infection with other diseases such as HIV and tuberculosis, presenting at health facilities with acute onset of respiratory illness ■ Patients who present at out patient departments (OPD) with symptoms of SARS-CoV-2 infection such as myalgia, fever, and fatigue etc⁹ but test negative for malaria, and are assessed and confirmed for absence of other febrile illness, should be routinely screened for COVID-19 symptoms and, if they meet the clinical criteria for COVID-19, should be prioritized for COVID-19 Ag rapid testing <p>Additional suggested populations</p> <ul style="list-style-type: none"> ■ High-risk household contacts of confirmed cases <p>Additional Populations to be considered during surge</p> <ul style="list-style-type: none"> ■ All symptomatic patients (high risk and general population) presenting or admitted at health facilities
<p>HIV clinics</p>	<p>Prioritized individuals</p> <ul style="list-style-type: none"> ■ Symptomatic PLHIV <p>Additional suggested populations</p> <ul style="list-style-type: none"> ■ PLHIV who are contacts of confirmed COVID-19 cases

9 Symptomatic individuals with low or no risk of severe illness to be managed as patients presenting with acute febrile illness

<p>TB & Respiratory clinics</p>	<p>Prioritized individuals</p> <ul style="list-style-type: none"> ■ All patients who present at the TB clinics should be screened for COVID-19 symptoms. If they meet the clinical criteria for COVID-19 testing, then COVID-19 test should also be provided in conjunction with TB services <p>Additional suggested populations</p> <ul style="list-style-type: none"> ■ TB patients who are contacts of confirmed COVID-19 cases
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- Operational interventions to ensure deliberate expansion of COVID-19 testing services within other diseases programmes, for example through diagnostic network optimization and integration to leverage existing laboratory and health systems to expand access to COVID-19 testing in places where PCR testing is used. Integration of laboratory systems includes cross-program coordination in human resource management, integrated quality management systems (proficiency testing panels, site supervision and mentoring), and sample transport systems. Diagnostic network optimization exercises are recommended to capitalize on available laboratory infrastructure and to achieve cross-program efficiency.
- Strengthening of human resources within HIV, TB and malaria disease programmes to improve knowledge and skills for managing COVID-19 testing, treatment and care. This can be fostered through trainings, targeted mentorships and supervision.
- Access to diagnosis for those at highest risk should be prioritized and establishment of referral pathways to access prompt treatment.
- The following deliberate efforts must be made to ensure that the following TB, and HIV services are integrated alongside COVID-19 testing services:
 - Modify TB, HIV services delivery models that persons living with HIV (PLHIV) to ensure easier and efficient access to COVID-19 testing as soon as needed, including access to self tests
 - Create awareness amongst PLHIV around COVID-19 symptoms, testing (including access to and use and interpretation of self tests) and establish mechanisms for PLHIV with COVID-19 infection to rapidly access to timely treatment to avert progression to moderate and severe disease
 - Ensure that PLHIV diagnosed and treated with COVID-19 are still able to access relevant care and adhere to their ART regimens
- Being diagnosed as COVID-19 positive may be a source of stigma and a factor deterring people from getting a test for fear of social consequences, fear of potential economic adverse effects such as risk for loss of employments, reduction in economic activities among others. Appropriate communication should be developed and implemented to ensure adequate sensitization and promotion of awareness among communities on COVID-19 including associated testing and treatment services integration into routine existing health services as far as possible.
- It is important for Member States to ensure relevant guidelines for ethical consideration are adhered to that recognize the importance of upholding human rights during the processes of integrating COVID-19 testing into routine healthcare services. Efforts should be made to:
 - Ensure there is no coercion of patients into 'mandatory' COVID-19 testing within health care facilities, but rather only for the health benefit of the patient. Provision of COVID-19 testing service should received by patients on voluntary basis.
 - Relevant efforts should be made to ascertain the relevant follow up treatment support or related access if required to confirmatory testing services are made available to all individuals who test positive for COVID-19 as per in-country protocols. Negative cases should be management appropriately in line with the essential national healthcare guidelines.

2.4 Diagnostic technology options at decentralized settings

Point-of-care nucleic acid tests and antigen-based rapid diagnostic tests are the more readily available technologies closer to patients at primary health care levels. WHO recommends the use of COVID-19 antigen tests with a minimum sensitivity of 80% and specificity of 97% and several low-costs rapid antigen tests with WHO Emergency Use Listing are available and in widespread use. In addition, rapid antigen self tests are now available and can be used within health facilities, within communities and at home. In addition, a number of health facilities have near point-of-care nucleic acid test capacity e.g GeneXpert, testing for TB and COVID-19 can be integrated by adopting strategies described in the STOP TB guide^{10,11}. Currently, multi-pathogen panel targeting SARS-CoV-2/Influenza A/B and RSV are available. In the future, additional affordable multi-pathogen point-of-care nucleic acid test technologies are expected to become available and these may facilitate further integration of COVID-19 with other disease testing services.

3.0 COVID-19 SURVEILLANCE FOR PUBLIC HEALTH PURPOSES

SARS-CoV-2 testing should continue to be integrated and enhanced within existing and new surveillance systems to monitor trends in COVID-19 transmission and identify potential surges that require timely response. Surveillance will help maintain the much needed visibility on the evolution of the virus that could impact future morbidity, mortality, and prevention and treatment options.

Using surveillance to inform decision-making and guide the effective implementation of public health and social measures (PHSM) for COVID-19, Africa CDC developed a strategy for [Enhanced COVID-19 Surveillance at the Community Level in Africa](#)¹² as well as a [COVID-19 Tiered Public Health and Social Measure Framework for Africa](#)¹³. These documents recommend enhancing existing or developing new surveillance, where feasible, for 1) community-based surveillance 2) sentinel surveillance and 3) wastewater surveillance.

If enhanced during phases of low to moderate incidence, surveillance efforts can be used to provide an early warning that can inform and enable timely implementation of PHSM to limit transmission of the virus, guide effective response to mitigate harm to communities, and monitor and detect potential emergence of COVID-19 variants of concern (VoC) through genomic surveillance¹⁴. This section focuses on enhancing SARS-CoV-2 testing recommendations for the above mentioned surveillance types as well as for primary healthcare facility surveillance, genomic surveillance, and seroepidemiological studies.

3.1 Community-based surveillance

Community-based surveillance (CBS) is a critical component of event-based surveillance and is useful for the early detection of individual cases and clusters of COVID-19 in communities. Community health workers (CHWs) play a critical role in the implementation of CBS. To enhance early identification of cases in the community, AU Member States should equip CHWs with COVID-19 screening and diagnostic tools, including self tests. Where possible, access to diagnostic services - ideally at nearby public health facilities or through self tests - should be prioritized for individuals at the community level. Further, community surveillance should particularly be enhanced in closed

10 <https://www.stoptb.org/file/9145/download>

11 https://www.theglobalfund.org/media/11438/covid19_tb-testing_briefingnote_en.pdf.

12 <https://africacdc.org/download/enhanced-covid-19-surveillance-at-the-community-level-in-africa/>

13 <https://africacdc.org/download/covid-19-tiered-public-health-and-social-measure-framework-for-africa/>

14 <https://africacdc.org/download/interim-operational-guidance-on-sars-cov-2-genomic-surveillance-in-africa-an-updated-guide/>

settings (e.g. schools, places of worship, clubs, prisons), camps (e.g. refugee, internally displaced, military) and within other settings hosting vulnerable populations (e.g. long-term care residences). Ensuring diagnostic delivery at the community level may reduce the potential burden in facilities offering primary care. Where possible, establishing or strengthening interoperability of community level diagnostic systems with existing HMIS systems should be encouraged to enhance early warning and response. Additional information regarding CBS for COVID-19 is available in the [Enhanced COVID-19 Surveillance at the Community Level in Africa](#).¹⁵

3.2 Sentinel surveillance

Organized, routine testing of populations at risk of infection of transmitting COVID-19, such as health care workers and teachers, has been shown to enable timely identification of emerging waves and even hot-spots of community transmission. Testing for sentinel surveillance within a static community (e.g. health care workers and teachers) can be performed as frequently as every two weeks in alignment with the incubation period of COVID-19 if country capacity can sustain this along with ongoing and increased pandemic response demands. The frequency should only be increased if testing capacity is adequate, as often during disease surges test supplies run low, and priority should be given to identifying symptomatic individuals. Individuals found positive should follow course of action outlined in existing national algorithms. Ideal sentinel surveillance targets can be found in the Annex and are elaborated in the [Enhanced COVID-19 Surveillance at the Community Level in Africa](#).¹⁶

Other forms of sentinel surveillance should also be explored. Many AU Member States have existing sentinel surveillance in place for influenza like illness (ILI) and severe acute respiratory infection (SARI). These systems are currently used to monitor respiratory illnesses like influenza and respiratory syncytial virus and have also been expanded to accommodate COVID-19 as well. [WHO End-to-End Integration of SARS-CoV-2 and Influenza Sentinel Guidance](#) provides detailed guidance on COVID-19 sentinel surveillance strategies that can be built into already existing systems like ILI/SARI¹⁷.

3.3 Wastewater surveillance

Surveillance testing on wastewater is conducted to detect rising community virus levels or the emergence of new or an increased number of variants. It also can be used as a surrogate measure that the virus levels are waning or no longer detectable in the community. Wastewater-based surveillance should be linked with existing wastewater monitoring programs, where implemented such as the Polio surveillance programmes, and be used to track multiple pathogens. Detailed guidance can be found in the Africa CDC recommendations for [Enhanced COVID-19 surveillance at community level in Africa](#).

3.4 Sequencing and genomic surveillance

Routine pathogen genome sequencing in combination with case surveillance is critical to identify the emergence of variants of interest and variants of concern. Information on these variants can inform public health risk assessment of increased virus transmissibility and disease severity, as well as decreased susceptibility to therapeutics, and decreased response to vaccine-derived immunity. Countries with limited capacity to perform sequencing are strongly encouraged to take steps to facilitate access to regional and international sequencing partnerships or increase their capacity through existing sequencing systems or laboratory networks. Additionally, Africa CDC is supporting countries to conduct SARS-CoV-2 genomic surveillance primarily for monitoring the emergence and spread of SARS-CoV-2 variants.

To be able to identify variants, an effort should be made to increase the representativeness of samples screened by sampling across different age bands, geographical distribution, different spectrum of disease, and clinically significant cases. This can be achieved through assigning [sentinel sites](#) across the country to conduct regular sampling.

15 <https://africacdc.org/download/enhanced-covid-19-surveillance-at-the-community-level-in-africa/>

16 <https://africacdc.org/download/enhanced-covid-19-surveillance-at-the-community-level-in-africa/>

17 https://www.who.int/publications-detail-redirect/WHO-2019-nCoV-Integrated_sentinel_surveillance-2022.1

3.5 Surveillance at primary care settings/facilities

Clinicians and all other health care workers are highly recommended to keenly keep an eye on sudden surges or clusters of respiratory infections. Thus, surveillance informed by SARS-CoV-2 testing, in primary care settings/facilities is needed to detect cases and clusters in the community. As testing should be available at primary health care facilities for improved access among symptomatic suspects, routine information on new cases can be readily captured and used to initiate appropriate control measures. At the primary care level, private facilities and laboratories provide a large proportion of the tests performed and should be included in the detection strategies and reporting systems. Digital reporting of test results from the primary care setting to national surveillance systems is recommended for rapid detection and response to a resurgence in cases, as well as to monitor treatment provision needs.

3.3 Sero-epidemiological surveillance of population immunity

Making data-driven decisions on the appropriate level of resources to allocate towards COVID-19 vaccination and other continued response efforts requires better tools to understand transmission at the population level. Representative cross-sectional sero-surveys can provide aggregate 'snapshots' of infection history and immunity, however one-off surveys are time-consuming to initiate, and the infrastructure for implementation is difficult to maintain over the long term. Countries are strongly encouraged to design and establish integrated platforms for sero epidemiological surveillance with a vision beyond COVID-19, to generate capacity for 'precision public health' to monitor both SARS-CoV2 transmission as well as additional major endemic diseases. Countries are encouraged to invest in establishing and maintaining bio-banks, and/or programs that use residual blood samples from health care facilities for routine, systematic, age-stratified determinations of COVID-19 immunity, that can also support broader immunization program goals. The data output will provide insights into how disease occurrence is interrelated with other health risk factors, and should be viewed as a critical pillar of pandemic preparedness efforts. The same repositories of biological specimens provide a critical resource to assess prevalence of novel pathogens if/when emergence or re-emergence episodes are suspected. The governance of such platforms will require coordination across multiple entities and may best be pursued through regional consortia of reference laboratories.

4.0 CROSS-CUTTING CONSIDERATIONS

Table 2 provides a set of considerations for maintaining adequate and effective testing capacity in the shift from emergency to sustainable control of COVID-19 and other priority diseases.

Table 2: Considerations for ensuring effective and sustainable diagnostic capacity for COVID-19

Additional Consideration	General Guidance
Policy and Governance	<ul style="list-style-type: none"> ■ Develop and implement policies and guideline for integration of COVID-19 into routine healthcare services ■ Regularly review and adapt national COVID-19 response contextualized with epidemiological changes in the pandemic ■ Mobilize and make available relevant resources essential for sustaining control of the COVID-19 pandemic
Emergence of COVID-19 testing technologies	<ul style="list-style-type: none"> ■ Develop and implement clear guidelines on adoption and use of new emerging testing technologies while ensuring that they address the integration COVID-19 testing and diagnosis of other diseases at all levels of health care
Procurement and Supply Chain Management	<ul style="list-style-type: none"> ■ Augment efforts to support procurement of quality COVID-19 testing supplies ■ Implement post-market surveillance to regularly monitor and evaluate the various diagnostic commodities to ascertain their quality and ensure they meet the specific test performance requirements ■ Ensure processes are in place for surge testing capacity in case of new pandemic waves
Human Resources	<ul style="list-style-type: none"> ■ Ensure an adequate healthcare workforce through deployment of additional healthcare service providers ■ Consider task-shifting of the healthcare service providers ■ Strengthen competencies of health care services providers through re-fresher trainings, mentorship and supervision
Quality Assurance	<ul style="list-style-type: none"> ■ Implement quality assurance¹⁸ at COVID-19 testing sites, integrated with other EQA programs ■ Conduct quality assessments at COVID-19 testing sites through implementation appropriate alternative approaches to quality assurance
Demand Creation	<ul style="list-style-type: none"> ■ Develop and implement communication campaigns to increase population awareness of COVID-19 testing
Data Management	<ul style="list-style-type: none"> ■ Support integration of COVID-19 testing into the routine healthcare data management and surveillance protocols (collection, reporting, analysis and dissemination)

18 <https://aslm.org/wp-content/uploads/2020/12/Quality-Assurance-Framework-for-SARS-CoV-2-Antigen-Rapid-Testing-for-diagnosis-of-COVID-19-Web.pdf?x55504>

5.0 MONITORING AND EVALUATION (M&E)

5.1 M&E metrics for COVID-19 testing programmes

The [KPIs for the revised Covid-19 Testing Strategy](#)¹⁹ (Annex-II) provides an outline of important M&E metrics that countries are encouraged to adapt to their local needs. A primary metric is the proportion of activated COVID-19 testing facilities as this is a measure of the accessibility of COVID-19 testing. Other metrics include the implementation of external quality assessment, the number of trained personnel providing COVID-19 testing, and the test positivity rate. COVID-19 M&E metrics should be integrated into M&E systems for other disease testing, such as HIV, TB and malaria.

19  [KPIs for the revised Covid-19 Testing Strategy](#)

ANNEXES

Annex I: List of Abbreviations and Acronyms

Africa CDC	Africa Centres for Disease Control and Prevention
Ag-RDTs	Antigen repaid diagnostic tests
AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral therapy
AU	Africa Union
CFR	Case Fatality Rate
CHWs	Community health workers
COVID-19	Coronavirus disease 2019
HIV	Human Immunodeficiency Virus
OPD	Out patient department
PACT	Partnership to Accelerate COVID-19 Testing
PLHIV	People living with HIV&AIDS
SARS-COV-2	Severe acute respiratory syndrome coronavirus 2
TB	Tuberculosis
TWGs	Technical working groups
VoC	Variant of concern
WHO	World Health Organization

Annex II : The Proposed KPIs


SN	Indicator*	Description	Numerator	Denominator	Target	Reporting Frequency
OBJECTIVE I: Integrating COVID-19 testing in routine healthcare services						
1.0 THE COVERAGE OF COVID-19 ROUTINE TESTING						
1.1	Percentage of facilities conducting COVID-19 testing	Proportion of health facilities public, private and others) conducting COVID-19 testing in country in the past 3 months	Total number of health facilities conducting COVID-19 testing in the last 4 months	Total number of health facilities in the country	≥95%	Quarterly
	1.1a. Molecular assays (PCR & Gene Xpert)	Proportion of health facilities (public, private and others) conducting COVID-19 testing in country using Molecular assays (PCR & Gene Xpert)	Total number health facilities conducting COVID-19 in country using Molecular assays (PCR & Gene Xpert)	Total number of health facilities in the country		Quarterly
	1.1b. Ag- RDT	Proportion of health facilities (public, private and others) conducting COVID-19 Ag- RDT testing in country	Total number of health facilities conducting COVID-19 Ag- RDT in country	Total number of health facilities in the country	≥95%	
1.2	% of ART sites offering COVID 19 testing in routine care	The proportion of ART sites in the country offering both HIV and COVID-19 testing services	Number of ART sites in the country offering both HIV & COVID-19 testing	Total number of ART sites in the country	≥95%	Quarterly
	1.3 % of TB clinics offering COVID-19 testing	The proportion of TB clinic in the country offering both TB & COVID-19 testing	Number of TB clinic in the country offering both TB & COVID-19 testing	Total number of TB clinics in the country	≥95%	Quarterly
2.0 THE QUALITY OF COVID-19 TESTING SERVICES						
2.1	2.1a. Percentage of laboratories conducting COVID-19 testing using Molecular assays (PCR & Gene Xpert) enrolled and participating in SARS-COV-2 proficiency test (PT) program(s)	Proportion of laboratories conducting COVID-19 testing in the country using Molecular assays (PCR & Gene Xpert) enrolled and participating in SARS-COV-2 proficiency Test program(s)	Number of laboratories in the country conducting COVID-19 testing using Molecular assays (PCR & Gene Xpert) enrolled and participating in a SARS-COV-2 Proficiency Test program (s)	Total number of laboratories in the country conducting COVID-19 testing using Molecular assays (PCR & Gene Xpert)	≥95%	Semi-annually

SN	Indicator*	Description	Numerator	Denominator	Target	Reporting Frequency
	2.1a. Percentage of COVID-19 testing laboratories using Molecular assays (PCR & Gene Xpert) enrolled on PT program(s) meeting acceptable performance	Proportion of COVID-19 testing laboratories using Molecular assays (PCR & Gene Xpert) in country enrolled on PT program meeting acceptable performance within the last 6 months	Number of COVID-19 testing laboratories using Molecular assays (PCR & Gene Xpert) enrolled on PT program(s) meeting the acceptable performance	Total number of COVID-19 testing laboratories using Molecular assays (PCR & Gene Xpert) in the country	≥95%	Semi-annually
2.2	Percentage of health facilities conducting COVID-19 Ag RDT receiving on-site supervision/assessment or implementing inter-laboratory comparisons <i>Noted: The SPI-RT checklist recommended as the tool for use for site assessments</i>	Proportion of health facilities conducting COVID-19 Ag RDT receiving on-site supervision/assessment or implementing inter-laboratory comparisons within the last 3 months	Number of COVID-19 Ag RDT facilities conducting COVID-19 Ag RDT receiving on-site supervision/assessment or implementing inter-laboratory comparisons	Total number health facilities conducting COVID-19 Ag-RDT in country	≥95%	Quarterly
	2.2a(ii) Percentage of COVID-19 Ag RDT testing facilities supervised/assessed that had acceptable performance of ≥80% (Level 3) <i>Note: Performance threshold of ≥80% is based on the SPI-RT Checklist threshold of ≥80%</i>	Proportion of COVID-19 Ag RDT testing sites supervised that had acceptable performance of ≥80% within the last 3 months	Number of COVID-19 Ag RDT testing sites supervised that had acceptable performance of ≥80% (Level 3)	Total Number of COVID-19 Ag RDT testing sites supervised	≥95%	Quarterly
3.0 VOLUME OF COVID-19 TESTING AND REPORTING						
3.1	Percentage of COVID-19 testing facilities reporting testing data	Proportion of COVID-19 testing facilities reporting testing data through the established national tier reporting system within the last 3 months	Number of COVID-19 testing facilities reporting testing data through the established national tier reporting systems	Total Number of COVID-19 testing facilities in country	≥95%	Quarterly
3.2	Number of performed COVID-19 tests reported	Volume of performed COVID-19 test reported within the last 3 months			N/A	Quarterly

SN	Indicator*	Description	Numerator	Denominator	Target	Reporting Frequency
3.3	3.2a Percentage of COVID-19 tests reported that were performed by Molecular assays (PCR & Gene Xpert)	Proportion of COVID-19 tests reported that were performed by Molecular assays (PCR & Gene Xpert)	Number of COVID-19 tests performed by Molecular assays (PCR & Gene Xpert) reported	Total number of COVID-19 tests performed Molecular assays (PCR & Gene Xpert)+ Ag RDT) reported	N/A	Quarterly
	3.2b Percentage of COVID-19 tests reported that were performed by Ag RDT	Proportion of COVID-19 tests reported that were performed by Ag RDT	Number of COVID-19 Ag RDT tests performed and reported	Total number of COVID-19 tests (PCR/ Gene Xpert + Ag RDT) performed and reported	N/A	Quarterly
	Percentage of positive COVID 19 tests	Proportion of COVID-19 tests reported positive	Number of COVID-19 positive test results reported	Total number of COVID-19 tests performed and reported	<5% Positivity	Quarterly
	3.3a %PCR	Proportion of COVID-19 RT-PCR tests reported positive	Number of COVID-19 positive RT-PCR tests reported	Total number of COVID-19 tests performed and reported	<5% Positivity	
	3.3b %RDT	Proportion of COVID-19 Ag RDT tests reported positive	Number of COVID-19 positive Ag RDT tests reported	Total number of COVID-19 tests performed and reported	<5% Positivity	
OBJECTIVE II: SARS-COV-2 SURVEILLANCE						
4.0 SENTINEL SURVEILLANCE						
4.1	Percentage of ILI/SARI sites in the country that have incorporated COVID-19 testing into routine influenza (flu-like illnesses) sentinel surveillance program	Proportion of ILI/ SARI sites in the country that have incorporated COVID-19 testing into their routine influenza/flu-like illness sentinel surveillance program	Number of ILI/ SARI sites in the country that have incorporated COVID-19 testing in their routine influenza/flu-like illness sentinel surveillance program	Total number of ILI/SARI sites in the country conducting influenza/ flu-like illness sentinel surveillance	100%	Semi-annually
5.0 GENOMIC SEQUENCING						
5.1	Number of positive COVID-19 specimens referred to national sequencing laboratory or regional sequencing hub	The volume of COVID-19 specimens referred to national or regional laboratories for sequencing to detect VoC	N/A	N/A	N/A	Quarterly
5.2	Percentage of sequenced samples with SARS-CoV-2 variants of concern (VoC) detected	Proportion of specimens sequenced with SARS-CoV-2 VoC detected	Number of sequenced samples with SARS-CoV-2 with VoC detected	Total number of samples sequenced for SARS-CoV-2 VoC	N/A	Quarterly

SN	Indicator*	Description	Numerator	Denominator	Target	Reporting Frequency
	5.2a Percentage of sequenced samples from <u>vaccinated individuals</u> with SARS-CoV-2 variants of concern (VoC) detected	Proportion of sequenced samples from <u>vaccinated individuals</u> with SARS-CoV-2 variants of concern (VoC) detected	Number of sequenced samples from <u>vaccinated individuals</u> with SARS-CoV-2 variants of concern (VoC) detected	Total number of samples sequenced SARS-COV-2 VoC	N/A	Quarterly
	5.2b Percentage of sequenced samples from <u>non-vaccinated individuals</u> with SARS-CoV-2 variants of concern (VoC) detected	Proportion of sequenced samples from <u>non-vaccinated individuals</u> with SARS-CoV-2 variants of concern (VoC) detected	Number of sequenced samples from <u>non-vaccinated individuals</u> with SARS-CoV-2 variants of concern (VoC) detected	Total number of samples sequenced SARS-COV-2 VoC	N/A	Quarterly
5.3	% of specimens rejected by the sequencing lab	Proportion of specimens referred for SARS-CoV-2 received at by the laboratories for sequencing that are rejected	Number of samples referred for SARS-CoV-2 sequencing received by the laboratory were rejected	Total number of samples referred for SARS-COV-2 sequencing received at sequencing laboratories	<1%	Quarterly

Africa Centres for Disease Control and Prevention (Africa CDC),
African Union Commission
Roosevelt Street W21 K19, Addis Ababa, Ethiopia

 +251 11 551 7700

 africacdc@africa-union.org

 www.africacdc.org

 [africacdc](https://twitter.com/africacdc)

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