African Union

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

Africa Centres for Disease Control and Prevention (Africa CDC)

Monitoring and Evaluation of COVID-19 Rapid Antigen Diagnostic Test Rollout in Africa

Introduction

Limited coverage of laboratory services and long turnaround times from real-time reverse transcription-polymerase chain reaction (rRT-PCR) for the detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) has been insufficient to meet the demands in many African countries in response to the COVID-19 pandemic. Rapid antigen diagnostic tests (Ag-RDTs) are potentially useful as they can inform healthcare workers and individuals of their infection status at point-of-care testing. Furthermore, Ag-RDTs are simple to perform and allow for the decentralization of SARS-CoV-2 testing and increase testing coverage; which can help reduce further transmission through early detection of highly infectious cases and ultimately enable a rapid start of contact tracing. Africa CDC has developed the interim guidance on the use of rapid antigen tests for COVID-19 response (https://africacdc.org/download/interim-guidance-on-the-use-of-rapid-antigen-tests-for-covid-19-response/) to improve access to testing and contribute to overall COVID-19 testing capacity, providing benefits in terms of shorter turnaround times, and reduced costs, especially in situations in which Real-time Polymerase Chain Reaction (RT-PCR) testing capacity is limited.

Africa CDC, African Society for Laboratory Medicine (ASLM) and partners have developed a training curriculum to facilitate the implementation of Ag-RDT for detection of SARS-CoV-2 (https://aslm.org/courses/covid-19-antigen-training-materials/). These training materials are being used by Member States for rollout training to health facilities. Training rollout is happening at the same time with the distribution of antigen-based rapid test kits. Africa CDC and partners have developed key indicators for monitoring the progress of the rollout of rapid antigen tests. Monitoring and evaluation of COVID-19 Ag-RDT rollout is essential for measuring progress in implementation. These indicators help to capture timely Ag-RDT implementation information and detailed COVID-19 test data from the COVID-19 Ag testing sites for better monitoring of the testing programme. The availability of real-time antigen testing data will help Member States to regularly generate evidence to drive national decision making on testing strategies. The selected indicators and reporting requirements are developed to track the progress of Ag-RDT testing in Member States.

Five indicators are selected based on their importance in measuring the rollout of COVID-19 Ag-RDT by the Member States. The first two indicators (indicators 1 and 2) will be monitored during the initial phase of Ag-RDT rollout. While the three indicators (indicators 3, 4, and 5) will be continuously monitored beyond the initial stage. Therefore, Africa CDC and partners recommended the following five key indicators to continuously monitor the implementation of Ag-RDT for the diagnosis of COVID-19 in AU Member States (Table 1).

Note: Member States may include additional indicators such as invalid test rate and turnaround time (TAT), etc., to be monitored at a national level. Invalid rate is a reportable indicator for post-market surveillance (by lot or batch of the test kit).

Indicator 1: Number of testing sites conducting COVID-19 test using Ag-RDT

As Ag-RDT can be performed at both the health and non-health facility level, including private facilities, it will be difficult to set a target in terms of the proportion of test sites performing Ag-RDT over the potential testing sites. Non-health facility testing sites such as workplaces, nursing homes and others, and private facilities can be considered as subcategories of **Indicator 1** and their data can be collected in absolute numbers by country.

In addition to the number of sites, Africa CDC recommends collecting the number of facilities offering COVID-19 testing and report the proportion of all COVID-19 facilities offering Ag-RDT in the country.

Indicator 2: Total number of personnel trained on Ag-RDT for COVID-19 testing

The number of personnel trained in Ag-RDT testing will be collected regardless of categories such as laboratory or nonlaboratory personnel, trainer or end-user (tester), etc. However, Africa CDC recommends the Member States and partners to collect this information segregated by category (i.e., laboratory personnel, nonlaboratory health care workers, and others at the national level.

Indicator 3: Percent of testing sites conducting Ag-RDT for COVID-19 enrolled in EQA

The number of Ag-RDT testing sites that have been enrolled in some form of the External Quality Assessment (EQA) scheme such as on-site supervision, re-testing (includes the exchange of samples between test sites), and proficiency testing (PT). The indicator measures a percentage of the total number of Ag-RDT sites registered with EQA out of the total number of sites performing Ag-RDT in the country (denominator is the number of testing sites stated in Indicator 1). Every country should target at least 75% of Ag-RDT testing sites to be enrolled in any form of EQA. At the moment, there is no PT provider identified for Ag-RDT.

Indicator 4: Test statistics

The total number of suspected individuals tested using Ag-RDT will be continuously reported to Africa CDC. This will not include those tested for follow-up purposes once they are positive. The report should include individuals tested during screening program in different settings (out of the usual health care or isolation centers).

Indicator 5: COVID-19 positivity rate (Inclusive of Ag and PCR)

A percentage of the number of individuals declared positive for COVID-19 using Ag-RDT and RT-PCR to the total number of individuals tested with those diagnostics. Indicator 5 should look across all test types, Ag-RDT and PCR (aggregate positivity rate); however, it should be further disaggregated by test types, COVID positivity rate for Ag-RDT (Indicator 5a) and COVID positivity rate for RT-PCR (Indicator 5b). The aggregated positivity rate (Indicator 5) is targeted at less than 5% but may vary depending on the prevalence of COVID-19 in the population tested and the pandemic transmission dynamics.

Indicator 5a is linked to **Indicator 4**. It can be calculated from test statistics as a percentage of the number of individuals declared positive for COIVD-19 using Ag-RDT over the total number of individuals tested with Ag-RDT. Similarly, Indicator 5b is defined as a percentage of the number of individuals declared positive for COVID-19 using RT-PCR over the total number of individuals tested with RT-PCR.

Table 1. Selected performance indicators for the rollout of Ag-RDT in the diagnosis of COVID-19

S/No.	Indicator*	Description	Numerator	Denominator
1.	Number of testing sites conducting COVID-19 testing using Ag RDT	Total number of Ag-RDT sites in the Member States during the reporting period	NA	NA
2.	Total number of personnel trained on Ag-RDT for COVID-19 testing	Total number of personnel trained on Ag-RDT during the reporting period	NA	NA
3.	Percent of testing sites conducting Ag RDT for COVID-19 enrolled in EQA	Number of Ag RDT sites enrolled in any form of the external quality assessment scheme	Total number of Ag RDT sites enrolled in EQA	Total number of Ag RDT performing sites in the country
4.	Test statistics	Total number of individuals tested using Ag-RDT during the reporting period	NA	NA
5.	COVID-19 positivity rate	Percentage of individuals reported as COVID-19 using Ag and RT-PCR	Number of individuals reported as COIVD-19 positive	Total number of individuals tested
5a	COVID-19 positivity rate for Ag-RDT	Percentage of individuals reported as COVID-19 positive using Ag-RDT	Number of individuals reported as COIVD-19 positive with Ag-RDT	Total number of individuals tested with Ag-RDT
5b	COVID-19 positivity rate for RT-PCR	Percentage of individuals reported as COVID-19 using RT-PCR	Number of individuals reported as COIVD-19 positive with PCR	Total number of individuals tested with PCR

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