



GUIDANCE ON THE USE OF ANTIGEN RAPID DIAGNOSTIC KITS FOR DIAGNOSIS OF SARS-CoV-2 INFECTION IN NIGERIA

Background

In September 2020, the World Health Organization (WHO) announced the EMERGENCY USE AUTHORISATION of two Antigen (Ag)-based rapid diagnostic tests (RDTs) by **SD Biosensor** and **Abbott** for COVID-19 testing.

Available WHO data on both RDTs show that they met the following minimal standards:

1. Ability to correctly identify individuals with the disease (Sensitivity >80%)
2. Ability to accurately identify those who do not have the disease (Specificity >97%)

Therefore, WHO recommends the use of Ag RDTs for:

- **Surveillance**- To detect individuals during the infectious phase to reduce the risk of transmission
- **Point of care tests**- RDTs are cheaper, have shorter Turn-Around Time (TAT) to detect localised outbreaks, isolate positive cases and stop transmission
- **Patient management**- RDTs have high sensitivity and quick TAT for use to triage patients and screen health workers

Ag RDTs are not recommended for use in low prevalence settings such as screening in airports or border crossings at ports of entry. The Ag RDT does not replace the use of the Polymerase Chain Reaction (PCR) and should be used in combination where required, depending on the epidemiological situation and clinical history of the individual. PCR remains the recommended test especially in areas with no or sporadic cases. **PCR remains the gold standard for testing.**

In Nigeria, only these WHO emergency approved AgRDTs are recommended for use and only for the scenarios below. We also recommend diligent collection of data on the use of these RDTs with NCDC approved tools for integration into the national database. This guidance will evolve as new evidence emerges.

CONTEXT OF Ag RDT USE IN NIGERIA

Following the WHO guidance on the use of these diagnostic devices, the Nigeria Centre for Disease Control (NCDC) recommends that these approved tests can be used in the following context in Nigeria. This is subject to approval for the use of these tests in Nigeria by the National Agency for Food and Drug Administration and Control (NAFDAC) as well as further validation of the tests by the Medical Laboratory and Science Council of Nigeria (MLSCN).

1. Use of AgRDTs to Screen for COVID-19 in Healthcare Settings

The AgRDTs can be used for the testing of health workers for COVID-19 and for testing of patients with symptoms of COVID-19 presenting in hospital triage areas. In both circumstances, a positive RDT test confirms the SARS Cov-2 infection. All Ag RDT negative cases are considered negative, however if COVID-19 like symptoms are present or persist, a PCR test should be done. AgRDTs can also be used to screen for COVID-19 in non-symptomatic patients before elective surgery and/or emergencies. If the RDT result is positive, perform a PCR test for confirmation. If RDT is negative, the patient is considered as negative.

2. Use of AgRDTs to Screen for COVID-19 among contacts of a PCR confirmed case

AgRDTs can be used for the testing of contacts of a PCR confirmed COVID-19 case. A contact who tests positive on using AgRDT, is considered confirmed for COVID-19. If AgRDT is negative, the person is considered as negative.

3. Use of AgRDTs to Screen for COVID-19 in Closed Settings

AgRDTs can be used as a screening test for students in boarding houses, prison inmates, National Youth Service Camps and other similar closed settings. In these closed settings, the first case in each setting that is positive with AgRDT should be retested with PCR for confirmation. Once one positive test has been confirmed by PCR, all subsequent AgRDT positive results are considered as confirmed and do not require retesting. This should be the case, until there is a 14-day (or more) gap between the recording of the last AgRDT positive case and a new case. All RDT negative cases are considered truly negative, if no SARS-CoV-2 symptoms persist.

4. Interpretation of RDT results

The performance and interpretation of Ag RDT results may differ in varying prevalence settings. In settings with high prevalence, for patients who test RDT negative and have COVID-19 like signs and symptoms and/or are close contacts of a case, testing should be repeated with PCR due to increased risk of false negatives. For patients with a positive RDT in a low prevalence setting, confirmation should be done by PCR due to the increased risk of false positives.

NOTE: To safeguard health workers, respiratory sample collection for any test from patients with suspected COVID-19 requires that operators wear gloves, gown, mask and face shield or goggles.