



NIGERIA CENTRE FOR DISEASE CONTROL

# GUIDANCE FOR THE USE OF APPROVED COVID-19 Ag-RDTs IN NIGERIA

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## PURPOSE OF DOCUMENT

The purpose of this document is to provide guidance to State Governments as well as other public and private institutions, on the use of Antigen (Ag)-based rapid diagnostic tests (RDTs) for coronavirus disease 2019 (COVID-19) diagnosis. Only RDTs that have been granted World Health Organization (WHO) Emergency Use Authorisation (EUA), and have been validated by the relevant national authorities, can be used in Nigeria.

## WHAT IS COVID-19 ANTIGEN (Ag) BASED RAPID DIAGNOSTIC TEST (RDT)?

Antigen (Ag) based RDT is a Point of Care (POC) test that detects the presence or absence of an antigen directly. This method is commonly used for the detection of a number of pathogens including SARS-CoV-2.

In September 2020, the World Health Organization (WHO) announced the EUA of two Antigen (Ag)-based Rapid Diagnostic Tests (RDTs) by **SD Biosensor** and **Abbott** for COVID-19 testing.

The available **WHO data on both RDTs show that they meet 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%)

The results from Ag-RDTs are usually generated in 10 to 30 minutes after the start of the analysis, providing a rapid means for COVID-19 diagnosis.

It is important to note that these Ag-RDTs are not as sensitive as molecular tests but can serve as a rapid means of identifying cases in settings where access to molecular testing is limited or impractical. The molecular-based polymerase chain reaction (PCR) test remains the goal standard for SARS-CoV-2 diagnostics.

Typically, all materials that are required to perform the test, including sample collection materials, are provided in the commercial kit, with the exception of a timer

## WHERE SHOULD Ag-RDTs for SARS-CoV-2 BE USED?

- Schools with accommodation facilities
- Office/workplace
- Hospitals for:
  - testing of health care workers who are exposed to a confirmed COVID-19 case
  - testing of patients with symptoms of COVID-19 presenting in hospital triage areas
  - testing of non-symptomatic patients before elective surgery and/or emergencies
  - testing of contacts of a confirmed case
  - periodic testing of health care workers
- Prisons
- National Youth Service Corps (NYSC) camps
- Other similar congregate settings

## PROCESS FOR TESTING

Currently, the authorised Ag-RDTs for SARS-CoV-2 require nasal or nasopharyngeal swab samples.

After collecting the respiratory specimen and applying it to the test strip, results are read by the operator within 10 to 30 minutes with or without the aid of a reader instrument. Appropriate personal protective equipment (PPE) should be worn by health workers involved in respiratory sample collection for any test from patients with suspected COVID-19. This includes gloves, gown, mask and face shield or goggles.

The person being tested should wait at a separate area, while testing and result interpretation is ongoing.

## PROCESS FOR DATA COLLECTION

All persons to be tested must fill the COVID-19 Testing Self Reporting Case Investigation Form (CIF) and provide

evidence at the point of sample collection. The CIF can be found on <https://rdt.ncdc.gov.ng/hospital>  
For support on this and data collection, please call **09062433395**

If the CIF has not been filled by the person to be tested, it should be completed prior to sample collection.

In areas with poor internet connectivity, the forms can be printed and filled, to be uploaded subsequently.

The test result should be entered into the result collection system – whether positive or negative.

**It is mandatory that details of patients and test results are submitted on the CIF Form, which will be integrated with the national COVID-19 surveillance system.**

## RESULT INTERPRETATION

All RDT-positive results should be interpreted as positive results. The patient should be counselled immediately and begin isolation. The national case management guideline should be adhered to.

If a person with symptoms or a high-risk contact of a positive case has a negative result, a PCR confirmatory test should be carried out to rule out COVID-19. The person should remain in self-isolation and managed appropriately until the PCR result is received.

If a person without symptoms has a negative result, this should be treated as a negative result. However, if the person has been in contact with a confirmed case, he/she should complete the 10-day self-isolation period.

## INFECTION PREVENTION CONTROL (IPC) STANDARDS FOR Ag-RDT SITES

- The RDT testing area should be in a designated space away from human traffic
- The space should be well-ventilated (windows open to the outside away from people with enough space to ensure physical distancing. Where feasible have clients sit outdoors with at least one metre distance between them and attend to individuals one at a time in the sample collection booth)
- There should be IEC material informing staff and patients informing them on appropriate use of face mask, hand hygiene and respiratory hygiene and cough etiquette and provisions made for patients and staff to practice these
- Appropriate personal protective equipment (PPE) should be worn by health workers involved in respiratory sample collection for any test from patients with suspected COVID-19. This includes gloves, gown, mask (or N95) and face shield or goggles
- Tests using Ag-RDT must be performed on an absorbent diaper or large paper towel in a well-ventilated area free of clutter, where there are no documents, computers or personal items.
- Staff responsible for sample collection as well as testing should be trained in and follow good microbiological practice and procedure (GMPP)
- Waste should be segregated appropriately. At the sample collection area and testing area, there should be at least two covered leg operated bins color coded red and black and lined with corresponding red and black bin liners
- The black lined bin should be used for the disposal of general waste that has not come into contact with any body fluid such as wrappings, cartons and packages of unused sample collection and RDT kits
- The red lined bin should be used for disposal of any item that has come in contact with any respiratory (nasal, oropharyngeal secretion) and any body fluids e.g. face masks, swabs and used cassettes
- The black bin should be disposed as municipal waste while the waste in red lined bin should be disposed as infectious waste preferably by incineration
- All staff handling any waste should wear appropriate PPE namely, face mask, disposable gloves under heavy duty gloves and apron
- All PPE should be disposed of appropriately as infectious waste and staff must be trained on appropriate donning and doffing of PPE followed by hand hygiene
- The sample collection and testing area should be cleaned and disinfected regularly, and at the end of each day. Sodium hypochlorite (bleach; for example, 1000 parts per million [ppm] (0.1%) can be used for general surface disinfection after cleaning with detergent and water
- For the clean up and management of spills, an absorbent material (cotton wool, tissue paper, paper towels)

should be used to mop up the spill into a red biohazard bag followed by cleaning with detergent and water and then disinfection with 10 000 ppm (1%) of bleach

### MINIMUM PERSONNEL REQUIRED

- Three sample collectors preferably all laboratory scientists. Where possible, there should be not more than one doctor or nurse who will also be responsible for counselling
- Four data clerks who will be responsible for filling out the CIF
- Two health assistants as cleaners
- Two environmental health officers or responsible personnel for fumigation

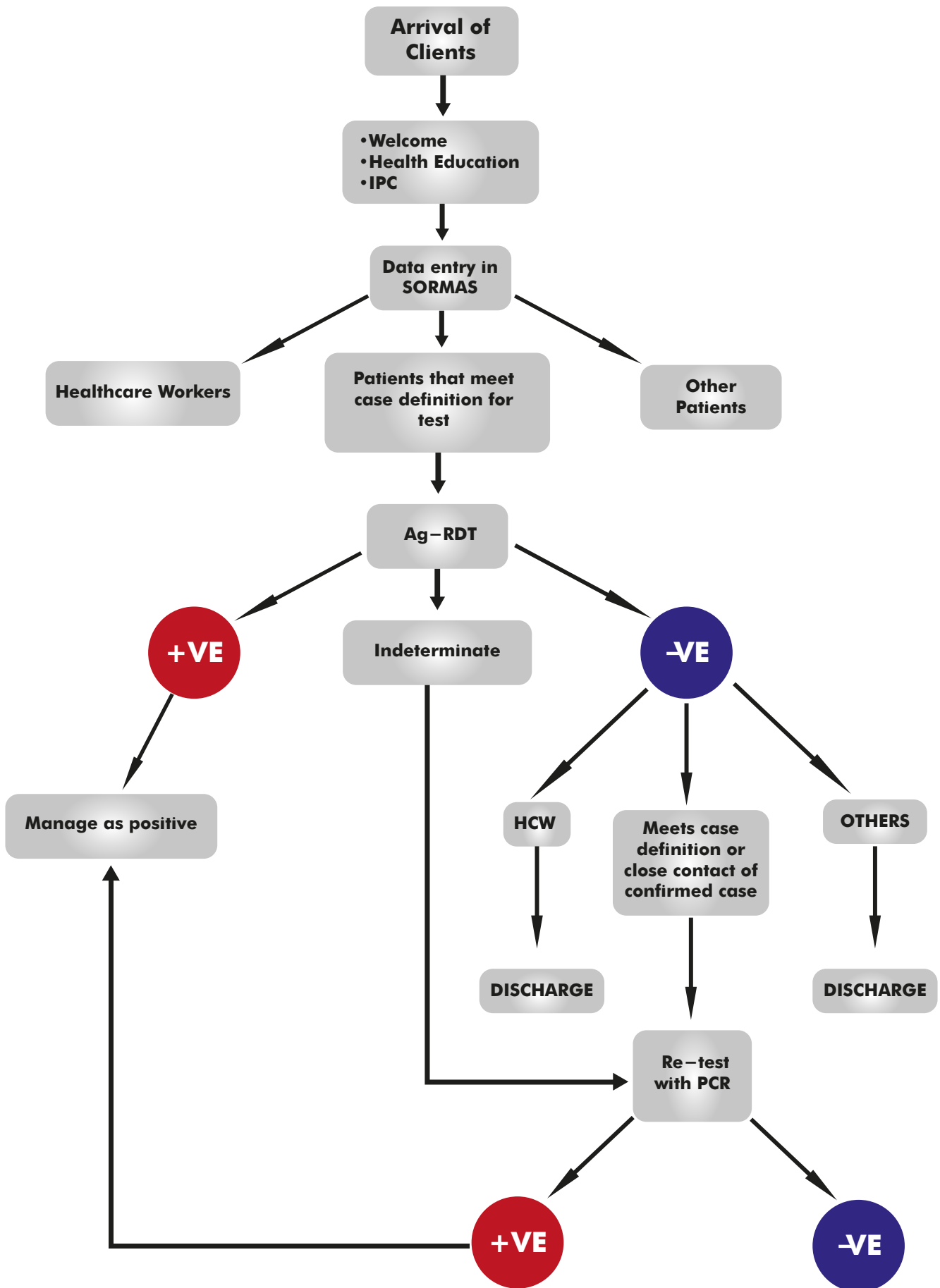
### RECOMMENDED PROCESS FLOW FOR SAMPLE COLLECTION AND TESTING SITES

1. A well-ventilated location such as an outdoor location well-barricaded and with tents, should be identified for sample collection and testing. This should be well-marked
2. Four areas should be well-defined
  - a. Welcome and data collection
  - b. Sample collection area
  - c. Waiting area post sample-collection
  - d. Testing area
3. All areas should have physical distancing measures in place such that seats are placed with a minimum of two-metres distance
4. On entry, patient's CIF should be reviewed for completion. If not filled, patient should be supported in filling this by the data clerk
5. The patient should be informed of the sample collection process, and his/her concerns related to testing should be addressed
6. Only one patient to be admitted at a time, to the sample collection point
7. Only trained laboratory personnel should be responsible for testing. Therefore, this area should be cordoned with access to only trained staff
8. When the result is received, patients should be informed with appropriate counseling provided by a trained health worker
9. Patients who test positive should be isolated immediately. The State Ministry of Health must be informed, and appropriate guidance will be provided
10. All results must be entered into the data collection system through SORMAS

For questions on this document, please contact [RDT@ncdc.gov.ng](mailto:RDT@ncdc.gov.ng)

#### Useful Links for further reading

1. [WHO SARS CoV2 Emergency use IVD list](#)
2. [Case Definition of COVID -19 Nigeria](#)
3. [National Case Management Guideline](#)





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