Republic of Rwanda
Ministry of Health

Rwanda Biomedical Centre
Healthy People, Wealthy Nation

Guideline for the use of Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays.

RATIONALE

Since the diagnostic of the COVID-19 outbreak in Rwanda, the Ministry of Health through its national laboratories networking has been using a real time reverse transcription polymerase chain reaction (rRT-PCR) assays, to detect SARS-CoV-2, the virus that causes the disease. In response to the growing COVID-19 spread, shortages of laboratory-based molecular testing capacity reagents and challenging turnaround time of testing of SARS-CoV.2; RBC has introduced a strategy of using reliable but less expensive and faster diagnostic tests that detect antigens specific for SARS-CoV-2 infection with reference to the guideline of World Health Organization on the use of Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. Regarding the requirements of quality management system, RBC has developed this guideline for the use of antigen rapid test for SARS-CoV-2 in Rwanda. This guideline will be regularly updated as new evidence becomes available.

GENERAL RECOMMENDATIONS FOR THE USE OF SARS-COV-2 ANTIGEN RAPID DIAGNOSTIC TEST(AG-RDT)

The SARS-CoV-2 Antigen Rapid Diagnostic Tests are immunoassays for the qualitative detection of the presence of specific SARS-CoV-2 antigen on nasopharyngeal or nasal swab specimens from patients with signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2.

SARS-CoV-2 Antigen Rapid Tests can also be used for screening testing in high-risk congregate settings in which repeat testing could quickly identify persons with a SARS-CoV-2 infection to prevent transmission. Antigen tests are relatively inexpensive and can be used at the point-of-care. The authorized antigen tests return results in approximately 15-30 minutes.

It is important for clinicians and testing personnel to understand and validate the performance characteristics, including sensitivity and specificity, of the particular rapid antigen test being used, and to follow the manufacturer's instructions and package insert.

The current gold standard for clinical diagnostic detection of SARS-CoV-2 remains Reverse Transcriptase Polymerase Chain Reaction (RT-PCR). Antigen tests for SARS-CoV-2 are generally less sensitive than RT-

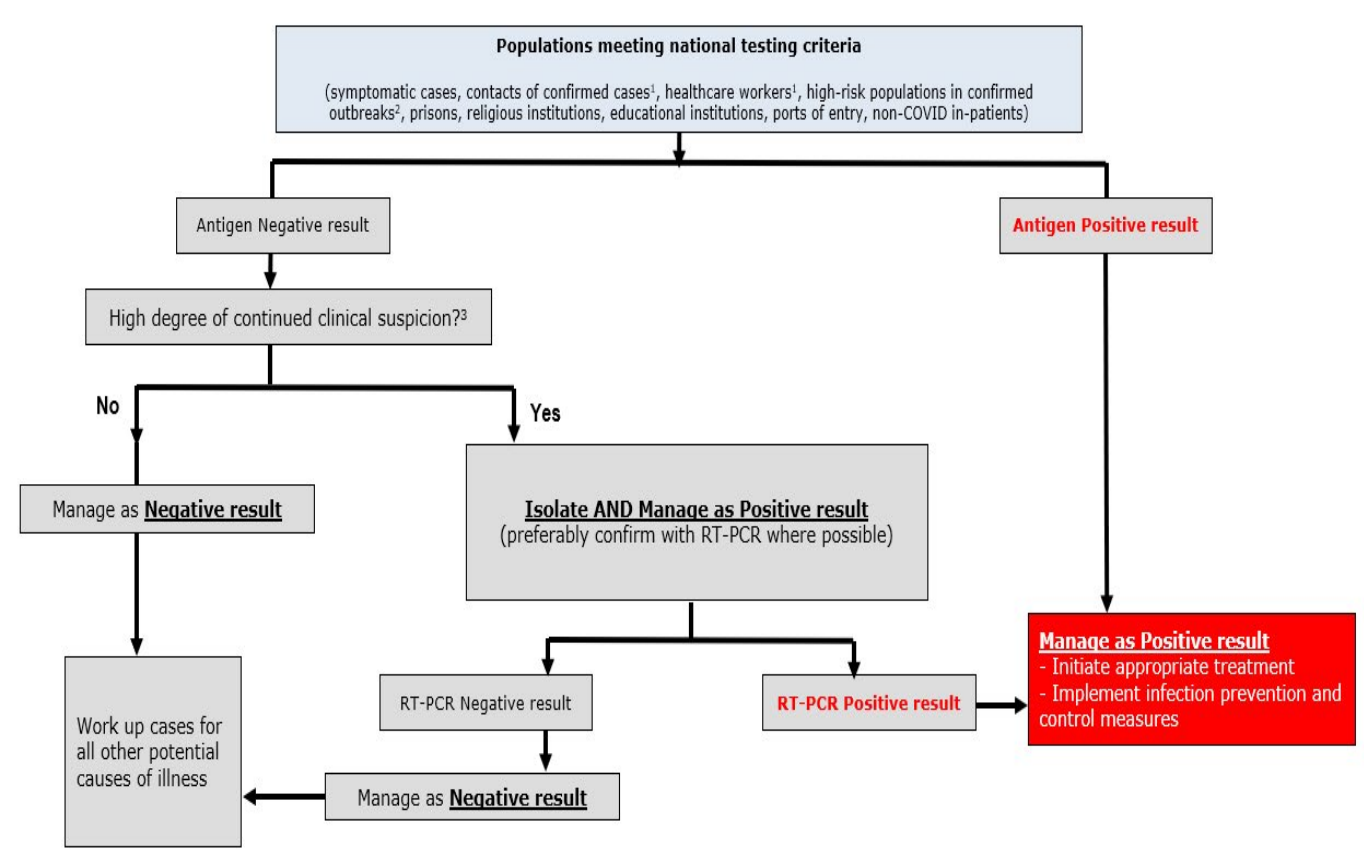
PCR. Thus, it may be necessary to confirm a rapid antigen test result with a RT-PCR test if the result of the antigen test is inconsistent with the clinical context.

When confirming an antigen test result with a RT-PCR test, it is important that the time interval between collection of samples for the two tests is less than two days, and there have not been any opportunities for new exposures between them. If more than two days separate the two collections, or if there have been opportunities for new exposures, the RT-PCR test should be considered a separate test – not a confirmatory test.

The National Reference Laboratory has the responsibility of validation of antigen rapid test of SARS-CoV-2 and demonstrates the sensitivity and specify in patients with recent infection (5 days post RT-PCR positive).

It is of note that Antigen levels in specimens collected beyond 5-7 days of the onset of symptoms may drop below the limit of detection of the test. This may result in a false negative test result, while a more sensitive test, such as RT-PCR, may return a positive result. It is therefore critical to implement the testing algorithm below in order to minimize false negative results.

1. Algorithm of testing SARS-CoV-2 using antigen rapid immunoassay



1. Symptomatic & asymptomatic 2. Includes elderly, people with comorbidities, populations in closed-settings (prisons, care homes, etc) 3. As determined by clinician based on patient clinical history. As per WHO "Continued clinical suspicion can, for example, be the absence of another obvious etiology, the presence of an epidemiological link, or suggestive clinical finding (e.g. typical radiological signs)."
4. For Invalid results, document invalid result, collect new sample and retest on Antigen test immediately. **Known positives are not to be tested with antigen RDTs

Use of Ag RDT SARS-CoV-2

Use of Antigen Rapid test are used in public and private health facilities, weddings, schools, prisons , churches or in other settings recommended by Ministry of Health.

RDT are intended for use in point of care settings by trained heath care or lab staff or trained operators who need to carry out sampling, testing, test analysis and reporting of tests results. Sample collectors will be required enter data within HMIS system and collect all information including results and indicating antigen rapid test as test conducted. The request of RDT will be done through RBC-National Reference Laboratory in order to ensure that sample collection, testing and result returned follow national guidelines.

COST OF Ag RDT SARS-CoV-2

The cost of each test is 10000Frw inclusive other service cost .Private clinic that intend to provide services will be need the approval of Ministry of Health to include the service. Private pharmacy are not provide the RDT.

COVID-19 SUSPECTED CASE DEFINITION

Clinical criteria:

- Acute onset of fever and cough
- Acute onset of ANY THREE OR MORE of the following signs or symptoms: *fever, cough, general weakness/fatigue, headache, myalgia, sore throat, coryza, dyspnoea, anorexia/nausea/vomiting, diarrhoea, altered mental status*

Epidemiological criteria:

- Very close contact of a positive case (stayed with a positive case for more than 30' within less than 1m distance without proper protection such as masks)
- Working in health setting, including within health facilities anytime within the 14 days prior to symptom onset

SARI (Severe Acute Respiratory Infection) case:

- A patient with severe acute respiratory illness (SARI: acute respiratory infection with history of fever or measured fever of ≥ 38 C°; and cough; with onset within the last 10 days; and who requires hospitalization)

REFERENCE

i. CDC, Interim Guidance for Rapid Antigen Testing for SARS-CoV-2, Updated Sept. 4, 2020
ii. WHO, Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays Interim guidance 11 September 2020