Implementation of COVID-19 rapid antigen detection test - *Pilot*

27 October 2020

This document provides practical considerations for the implementation of COVID-19 rapid antigen detection test (Ag-RDTs) in the Region of the Americas. General considerations for the use of Ag-RDTs in the diagnosis of SARS-CoV-2 infection have been published (1, 2) and several assays have been independently evaluated and/or listed in the WHO Emergency Use Listing[1]. Scientific and technical evidence on SARS-CoV-2 infection detection is evolving rapidly; this document will be updated as necessary.

1. User cases

In general, SARS-CoV-2 Ag-RDTs that meet the performance requirements (sensitivity ≥80% and specificity ≥97% compared with a reference molecular assay) can be used to diagnose SARS-CoV-2 infection in settings where molecular testing (e.g., rRT-PCR) is limited or unavailable, or where it is available with prolonged turnaround times (1). Additionally, Ag-RDTs should be in general less expensive than PCR tests; therefore, a reduction in diagnostic costs might be expected.

The following user cases might be considered:

i. First and second level of care in remote areas with no or very limited access to molecular testing.
ii. First and second level of care in areas with access to molecular testing but turnaround times longer than 72 hours.
iii. Triage of symptomatic patients.
iv. Symptomatic health care workers when molecular testing is not timely available.

Given their better performance during the early stages of the acute phase of the infection when viral replication is higher, Ag-RDTs **should be prioritized for symptomatic patients** within 10 days of symptom onset (preferably, within 5-7 days of symptom onset), and eventually in contacts of confirmed patients in selected settings (closed environments or households where high risk individuals might get infected). **Their use for screening of asymptomatic individuals at ports of entry or in the community is currently not recommended** (1). Countries should carefully assess the user cases that might correspond the best to their testing needs.

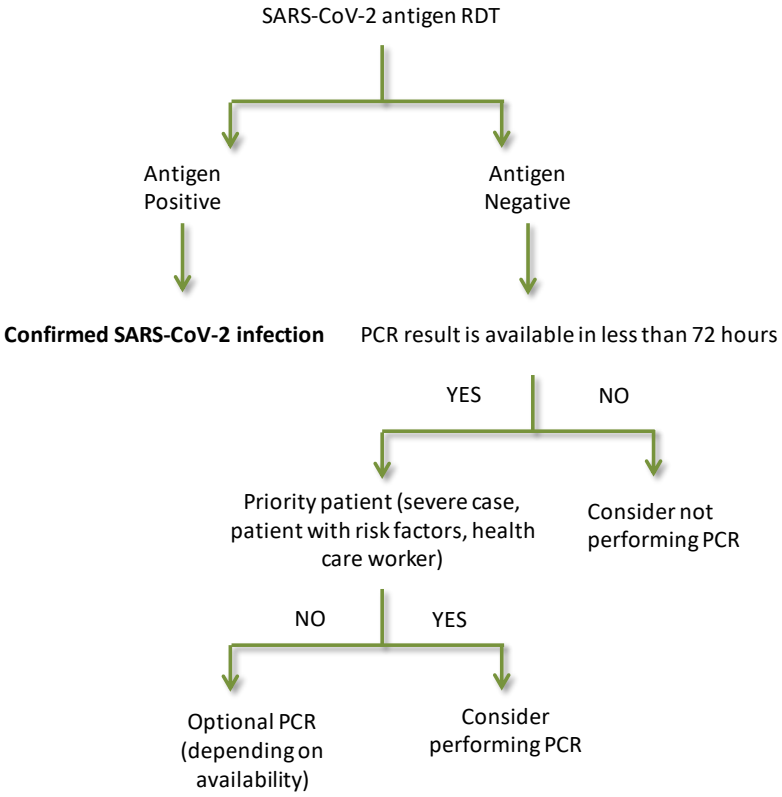
2. Result interpretation

Ag-RDTs results should be interpreted in the context of clinical and epidemiological information. As for any diagnostic assay, positive and negative predictive values vary significantly with the level of disease prevalence in the tested population (1). In high-prevalence populations (e.g., symptomatic patients in areas where SARS-CoV-2 is known to circulate), Ag-RDTs can be considered confirmatory and patients with positive test results should be isolated and clinically managed as required.

[1] FIND Evaluation of Sars-CoV-2 Antigen (Ag) Detecting Tests (https://www.finddx.org/covid-19/sarscov2-eval-antigen/) and WHO Emergency Use Listing for SARS-CoV-2 in vitro diagnostic products (https://www.who.int/diagnostics_laboratory/EUL/en/)

Nevertheless, given the expected sensitivity of Ag-RDTs, a negative result **does not necessarily rule out a possible infection**, and clinical and epidemiological information should also be considered to guide the implementation of public health measures. If available, molecular testing might be considered for symptomatic antigen-negative patients, particularly in priority/high risk patients depending on the clinical and epidemiological criteria.

The following algorithm might be used to guide the use of PCR testing in symptomatic antigen-positive and -negative cases (see 1. User cases). This algorithm should be adapted to national or local conditions.



3. Reporting

Test results should be reported following national guidelines and considering the existing surveillance data reporting protocols. Results generated using Ag-RDTs should be considered separately than those generated using molecular tests; therefore, the necessary adjustments should be done.

Additional information might be collected when implementing Ag-RDTs to monitor usage, performance, and impact:

- Patient identifier, age, sex
- Type of patient (symptomatic / contact)
- Date of symptom onset (symptomatic cases) / Date of last contact (contacts)
- Date/time of sample collection
- Type of sample collected (nasopharyngeal swab collected in kit extraction buffer / collected in viral transport medium)
- Type of test, type of reader (if used)

- Test lot number
- Date/time of result
- Test result (incl. quantitative reading if a reader is used)
- Follow-up
    - symptomatic cases: isolation, referral, hospitalization, number of contacts tracked
    - contacts: quarantine, follow-up for symptoms
- Shipment of sample for molecular testing
    - Date of shipment
    - Sample identifier
    - Laboratory
    - Date of molecular test result received
    - Molecular test result (incl. protocol used and Ct value)

4. Biosafety considerations

The biosafety guidelines for point of care (POC) or near-POC assays (3) and manufacturer's instructions should be followed. A local risk assessment should be performed. Assays could be performed on a diaper or large paper towel in a **well-ventilated** area free of clutter using the appropriate personal protective equipment (PPE): disposable gloves, full-length laboratory coats/gowns, eye (goggle) or facial (face shield) protection, and surgical mask. The use of a biosafety cabinet is optional.

PPE requirements for sample collection have been published (4).

Handle laboratory waste from testing suspected or confirmed COVID-19 patient specimens as all other biohazardous waste in the laboratory. For disinfection, incl. general surfaces and sample spills, appropriate disinfectants with proven activity against enveloped viruses should be used (for example, hypochlorite, alcohol, hydrogen peroxide, quaternary ammonium compounds, and phenolic compounds) (3). Particular attention should be paid to the selection of the disinfectant, dilution, contact time, shelf-life and expiry date after the working solution is prepared.

References

1. World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. Interim guidance. 11 September 2020. WHO/2019-nCoV/Antigen_Detection/2020.1. Geneva: WHO; 2020. Available from: https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays.

2. World Health Organization. Diagnostic testing for SARS-CoV-2. Interim guidance. 11 September 2020. WHO/2019-nCoV/laboratory/2020.6. Geneva: WHO; 2020. Available from: https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2.

3. World Health Organization. Laboratory biosafety guidance related to coronavirus disease 2019 (COVID-19). WHO/WPE/GIH/2020.3. Geneva: WHO; 2020. Available from: https://www.who.int/publications-detail/laboratory-biosafety-guidance-related-to-coronavirus-disease-2019-(covid-19).

4. Pan American Health Organization / World Health Organization. Requirements and technical specifications of personal protective equipment (PPE) for the novel coronavirus (2019-ncov) in healthcare settings, Interim recommendations. Washington, DC: PAHO / WHO; 2020. Available from: https://www.paho.org/en/documents/requirements-and-technical-specifications-personal-protective-equipment-ppe-novel.