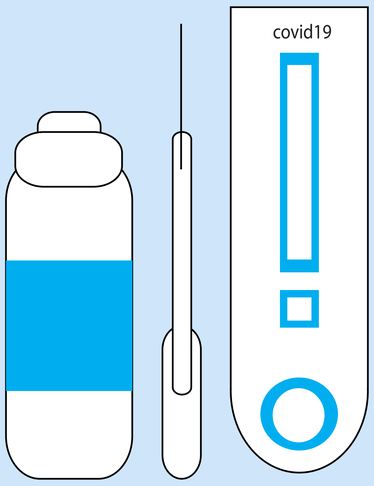
GENERAL RECOMMENDATIONS FOR THE USE OF COVID-19 ANTIGEN-BASED RAPID DIAGNOSTIC TESTS

World Health Organization
REGIONAL OFFICE FOR Africa



01 Antigen-Rapid diagnostic tests that meet minimum performance requirements

Antigen-based rapid diagnostic tests that meet the minimum performance requirements of ≥ 80% sensitivity and ≥97% specificity compared to a NAAT reference assay[1] can be used to diagnose SARS-CoV-2 infection in a range of settings **where NAAT is unavailable or where prolonged turnaround times preclude clinical utility**.

02 Ag-RDT testing performance optimization

To optimize performance, testing with Ag-RDTs should be conducted by trained operators in strict accordance with the manufacturer's instructions and within the first 5-7 days following the onset of symptoms.

03 Appropriate scenarios for use of COVID-19 Ag-RDTs include the following:

Respond to suspected outbreaks of COVID-19

To respond to suspected outbreaks of COVID-19 in remote settings, institutions and semi-closed communities, where Nucleic acid amplification testing (NAAT) is not immediately available. Where possible, all samples giving positive Ag-RDT results (or at least a subset) should be transported to laboratories with NAAT capability for confirmatory testing.

Support outbreak investigations

To support outbreak investigations (e.g. in closed or semi-closed groups including schools, care-homes, cruise ships, prisons, work-places and dormitories, etc.) In NAAT-confirmed COVID-19 outbreaks, Ag-RDTs could be used to screen at-risk individuals and rapidly isolate positive cases (and initiate other contact tracing efforts) and prioritize sample collection from RDT-negative individuals for NAAT.

Monitor trends in disease incidence

To monitor trends in disease incidence in communities, and particularly among essential workers and health workers during outbreaks or in regions of wide spread community transmission where the positive predictive value and negative predictive value of an Ag-RDT result is sufficient to enable effective infection control.[2]

Test where there is widespread community transmission

Where there is widespread community transmission, RDTs may be used for early detection and isolation of positive cases in health facilities, COVID-19 testing centres/sites, care homes, prisons, schools, front-line and health-care workers and for contact tracing.

Test of asymptomatic contacts

Testing of asymptomatic contacts of cases may be considered even if the Ag-RDT is not specifically authorized for this use, since asymptomatic cases have been demonstrated to have viral loads similar to symptomatic cases, though in that situation, a negative Ag-RDT should not remove a contact from quarantine requirements.

04 Initial introduction of Ag-RDTs into clinical use

Countries should consider selecting some settings where NAAT confirmatory testing is currently available so that staff can gain confidence in the assays, confirm performance of the selected RDT, and troubleshoot any implementation issues encountered.

05 Situations where confirmatory testing with NAAT is not feasible

Any indications that results may be incorrect should raise suspicions about validity. Examples would include patients who are test-positive but have a clinical syndrome not consistent with COVID-19, or patients with a positive test detected in a low-prevalence setting (where the predictive value of a positive test is low and the risk of false-positives high). Other warning signals might include patients who are test-negative but have a classical syndrome, are close contacts of a case or are tested in a high-prevalence setting.

06 Use of Ag-RDTs is not recommended in

Settings or populations with low expected prevalence of disease (e.g. screening at points of entry, blood donation or for elective surgery), especially where confirmatory testing by NAAT is not readily available. Such use will not be possible until there are more data from high-quality studies confirming high specificity (>99%) of one or more of the commercialized Ag-RDT test kits.

1 Based on well-designed and executed evaluations in representative populations.
2 Risk of false positive results is high in low prevalence settings; positive predictive value is 78% if prevalence is 10% minimum performance criteria met; increases to 93% if prevalence is 20%

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