

Guidance for Implementation of Antigen Rapid Diagnostic Tests for COVID-19

1. Introduction

Countries in the WHO African region continue to battle the COVID-19 pandemic. To effectively stop the spread of SARS-CoV-2 or COVID-19, it is necessary to rapidly detect all positive cases of COVID-19 for isolation, treatment and implementation of public health control measures based on the national protocols. In general, National Testing Strategies should be formulated in consultation with epidemiology, surveillance and case management counterparts and the strategy should aim to use available resources to achieve maximum public health impact.

As we have observed in many countries, the pandemic is dynamic and a surge could occur in any country at any time. With this in mind, countries and response plans need to be nimble and adaptable to the evolving situations to ensure mitigation of transmission.

This document aims to guide countries on the implementation and roll out of antigen rapid diagnostic tests as an alternative to nucleic acid amplification testing (NAAT).

2. Testing for SARS CoV-2

WHO recommends that all individuals suspected of being infected with SARS CoV-2 be tested. The “gold standard” for COVID-19 detection is nucleic acid amplification testing (NAAT) where viral genomes are detected indicating the presence of the virus in an individual. However, due to the extensive requirements for NAAT such as infrastructure, human resources, equipment and reagents it is unlikely that PCR this will be available in all areas.

Due to the constraints of PCR, countries are strongly encouraged to initiate the use of Antigen Rapid Diagnostic Tests (Ag-RDT) to rapidly detect infection and to guide the implementation of adequate public health control

measures. Unlike PCR, Ag-RDT are:

- less expensive (\$3.00 or less per test) compared to PCR, no additional reagents or consumables required;
- able to produce patient results in 15 to 30 minutes;
- easy to use - no complex manipulations required;
- suitable for any setting where biosafety measures are ensured and storage conditions for tests are suitable.

There are many Ag-RDT available in the marketplace so there is a wide variety of choice when deciding which Ag-RDT to purchase. When selecting an Ag-RDT for use it should meet the **minimum specifications set by WHO for sensitivity ($\geq 80\%$, desirable $\geq 90\%$), and specificity ($\geq 97\%$, desirable $>99\%$), when compared to an approved NAAT in symptomatic populations.** Currently there are 4 Ag-RDT that have been WHO Emergency Use Listed (Annex 1). All are available through the COVID-19 Supply Catalogue (<https://www.who.int/publications/m/item/emergency-global-supply-chain-system-covid-19-catalogue>)

3. Transmission based scenarios for use of Ag-RDT

In all situations testing with Ag-RDT should be:

- performed by trained individuals
- in accordance with the manufacturers’ instructions
- within the first 5-7 days following the onset of symptoms

The type and intensity of transmission of SARS-CoV-2 in the population being tested will affect the positive and negative predictive values (PPV and NPV) of the tests and the likelihood of false-positive or false-negative results,

which may impact your testing strategy¹. In populations with few or no cases, it is preferable to use NAAT, as it is more sensitive. Where the number of cases is increasing, or there is widespread community transmission, the PPV increases it may be more effective to use tests that can be

performed in any setting, are less resource intensive and can be used closer to the patient, such as Ag-RDTs. Four transmission scenarios are commonly described as indicated below. The choice of test to use in these different scenarios is listed in the Table 1.

Table 1. Transmission based scenarios for the use of Ag-RDT

Transmission Scenario		Test positivity rate threshold	Case incidence threshold (No. of new cases per 100,000 population)	Suggested Test to Use (if available and dependent of capacity)	Who to Test
No cases		0%	0	NAAT [^]	<ul style="list-style-type: none"> ○ Test all individuals meeting the suspect and probable case definition and high-risk asymptomatic contacts of confirmed or probable cases and frequently exposed people such as health care workers and long-term care facility staff.
Sporadic cases		~0%	~0	NAAT [^]	
Clusters of cases		<1%	<10	NAAT [^]	
Community transmission	CT1	< 2%	< 20	NAAT and/or Ag-RDT*	
	CT2	2 - <5%	20 - <50	NAAT and/or Ag-RDT*	<ul style="list-style-type: none"> ○ Test patients with unexpected clinical presentation or an increase in hospital admissions in a specific demographic group that could be COVID-19. ○ Test all or a subset of samples from SARI/ARI/ILI surveillance for SARS-CoV-2.
	CT3	5 - <20%	50 - <150	NAAT and/or Ag-RDT*	
	CT4	20%+	150+	NAAT and/or Ag-RDT*	

SARI, severe acute respiratory syndrome; ARI, acute respiratory syndrome; ILI, influenza like illness; SOP, standard operating procedure; NAAT, nucleic acid amplification test; Ag-RDT, antigen-detecting rapid diagnostic test

[^] if location does not have reasonable accessibility to NAAT (result turn around <48h) then alternatives such as Ag-RDT should be considered for symptomatic individuals. Please refer to Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays (<https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays>) for guidance on the use of Ag-RTD in low prevalence settings

****Depending on the setting and/or the context of the individual being tested a negative Ag-RDT test may be considered as presumptive and further actions should be taken with respect to testing and public health interventions.***

Suggested interventions may include:

- Communicate risk, promote infection prevention and control actions and physical distancing;
- Monitor for symptoms and re-test if symptoms develop;
- Refer for molecular testing (if available) if symptomatic and quarantine until molecular tests result is available;
- Advise on clinical care if symptomatic
- If molecular testing is not available, quarantine and re-test with Ag RDT after 5 days.

¹ Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays (<https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays>) for guidance on the use of Ag-RTD in low prevalence settings

4. Case based scenarios for use of Ag-RDT

Complementing the transmission scenarios for use of Ag-RDT are “use based” scenarios as described below. These should be used in combination or to complement transmission-based scenarios so as to capture as many people as possible to be tested.

Table 2. Use based scenarios for the implementation of Ag-RDT

Situation	Population to be tested
Symptomatic individuals	Testing symptomatic individuals and those who fit the COVID-19 case definition (https://www.who.int/publications/i/item/WHO-2019-nCoV-Surveillance_Case_Definition-2020.2)
Asymptomatic Individuals, those who are <ul style="list-style-type: none"> ▪ high-risk or ▪ highly exposed 	Testing of asymptomatic individuals who are contacts of confirmed or probable cases, people coming from high risk area, front line workers (e.g police, customs and immigration) front line health care workers and ancillary health facility workers, and testing those in care homes, prisons and/or schools if a confirmed COVID-19 case has been identified in the institutions,
Outbreak Investigation	In remote settings, institutions and semi-closed communities (NAAT not available)
Supporting Outbreak Investigation	Screening at risk individuals in closed or semi-closed settings where an outbreak of COVID-19 has been confirmed
Monitoring Disease Incidence	Monitoring disease trends in symptomatic individuals

5. Implementation in the field - utilization of IDSR

Integrated Disease Surveillance and Response is the cornerstone of communicable and non-communicable disease surveillance in the region and all countries have implemented IDSR for at least 1 condition. The IDSR guidelines outline syndromic surveillance for respiratory disease by applying standard case definitions for Influenza Like Illness (ILI) and Severe Acute Respiratory Illness (SARI) (Table 3).

Countries are strongly encouraged to **implement respiratory disease surveillance as outlined in IDSR version 3 at all IDSR sites and health facilities** so as to capture COVID-19 infections anywhere at any time.

Currently sentinel sites for influenza surveillance can be easily adapted to COVID-19 surveillance and guidance is available to support implement or adaptation of influenza surveillance to include COVID-19 ([https://www.who.int/publications/i/item/maintaining-surveillance-of-influenza-and-monitoring-sars-cov-2-adapting-global-influenza-surveillance-and-response-system-\(gisrs\)-and-sentinel-systems-during-the-covid-19-pandemic](https://www.who.int/publications/i/item/maintaining-surveillance-of-influenza-and-monitoring-sars-cov-2-adapting-global-influenza-surveillance-and-response-system-(gisrs)-and-sentinel-systems-during-the-covid-19-pandemic)).

In this regard Ag-RDT as a means of detection of COVID-19 in this context and should be strongly considered.

Table 3. Case definitions for Influenza like illness and Severe Acute Respiratory Infection

	Influenza Like Illness (ILI)	Severe Acute Respiratory Infection (SARI)
Sites where individuals are captured	Outpatient/ambulatory clinics	Hospitals, Inpatient settings
CASE DEFINITION	<ul style="list-style-type: none"> ○ measured fever of 38 °C or more, AND ○ cough ○ with onset within past 10 days 	<ul style="list-style-type: none"> ○ history of fever or measured fever of 38 °C or more AND ○ cough ○ with acute onset within past 10 days AND ○ requires hospitalization

6. Forecasting ensuring adequate supplies

The ongoing need for supplies is not easy to predict, especially with the changing landscape of the pandemic and each country being unique in their situation. The OSL team have developed the *Essential Supplies Forecasting Tool* which is available at the following URL

<https://www.who.int/publications/i/item/WHO-2019-nCoV-Tools-Essential-forecasting-2021-1>. Please consider using this tool to anticipate needs over the next 6 to 12 months so that interruption in supplies do not occur. Please note that there is an emergency supply of swabs,

swabs/VTM and Ag-RDT at the WHO Regional Office to fill gaps due to hold ups in delivery of orders or other reasons. However, this supply does not replace orders and only small quantities will be dispatched based on requests and needs. It is therefore advised that countries utilize the forecasting tool to quantify needs and place orders accordingly.

7. Actions for Implementation and Surge

The possibility for a third wave of the pandemic is tangible as has been observed in India. The risk of a third wave or resurgence of COVID-19 in Africa remains high for all African countries due to poor adherence to public health measures, mass gatherings and low testing and vaccination rates. The widespread use of low cost and rapid diagnostics coupled with implementation of and adherence to public health counter measures is critical to mitigate the effects of a resurgence as the ability to

rapidly detect infected individuals and implement public health actions is greatly enhanced, thereby limiting further transmission.

Some activities that could be planned for or initiated in advance of the resurgence include:

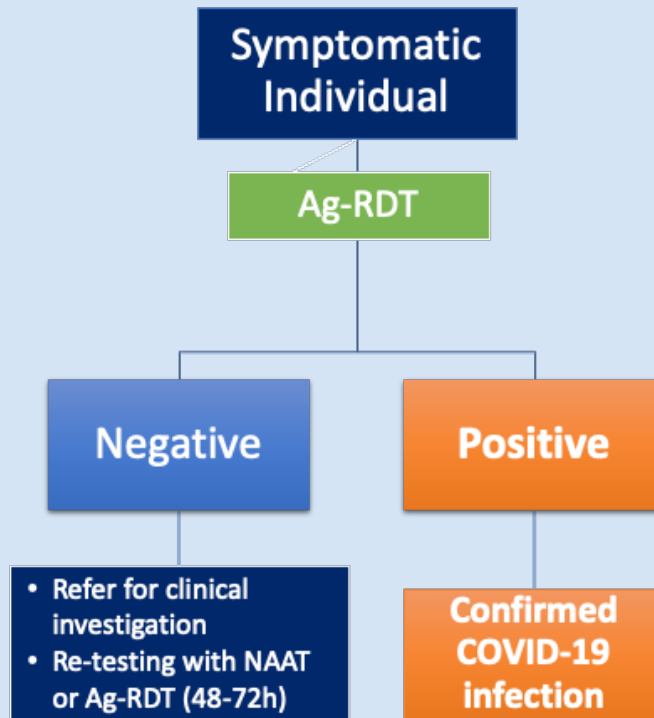
- Expansion of localized testing facilities.
- Supply chain and storage conditions adapted to accommodate Ag-RDT (12 month shelf life if stored in optimal conditions, maximum storage temperature 30)
- Introduction of mobile sampling and testing facilities.
- Identification of sources of surge staff for PCR testing and/or Ag-RDT testing
- Familiarization of health workers on case definitions for ILI/ARI and SARI
- Cascade Ag-RDT training to all levels of the health system and communities.

Annex 1: Ag-RDT Emergency Use Listed by WHO

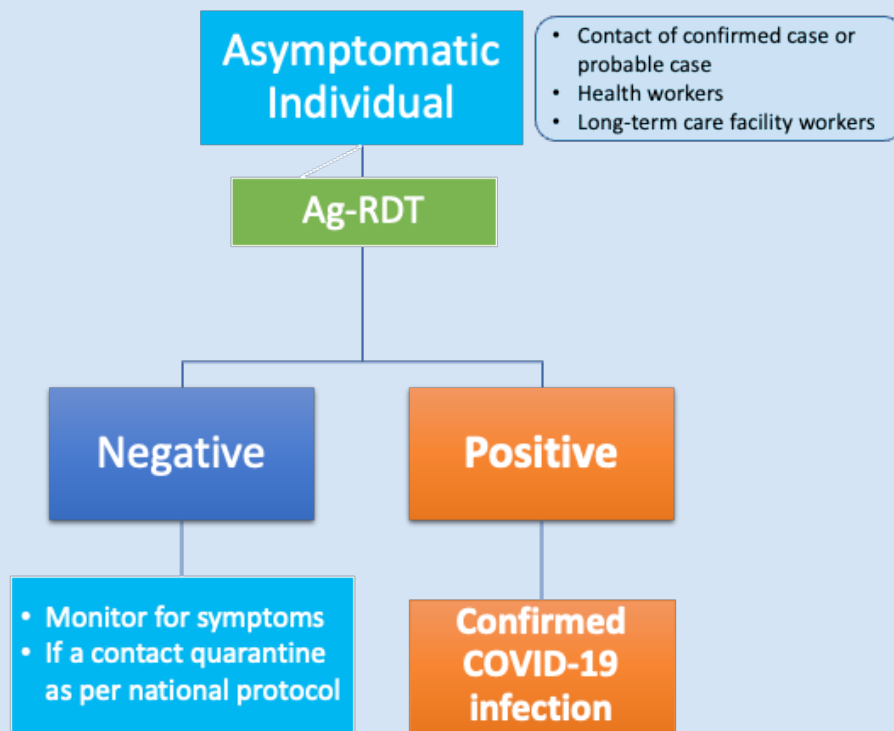
Product	Country	Ag Detected	Specimen
Abbott PanBio COVID-19 Ag Rapid Test Device	US	NC	Nasal
Abbott PanBio COVID-19 Ag Rapid Test Device	US	NC	Nasopharyngeal swab
SD Biosensor STANDARD Q	South Korea	NC	Nasopharyngeal swab
Sure Status COVID-19 Antigen Card Test*	India	NC	Nasopharyngeal swab

Algorithms for use of Ag-RDT

Algorithm 1 – Symptomatic individual



Algorithm 2 – Asymptomatic Individuals



References

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