

The Tenth Protocol: Guidelines for International and Local Travellers⁹⁹:

Introduction:

The World Health Organization (WHO) recommends a comprehensive approach to supporting and managing travelers before departure and on arrival, which includes a combination of measures for consideration before departure as well as on arrival destination.

This guideline is customized from the “*WHO guideline on public Health Considerations while resuming international travel*” which was published on July 30th, 2020.

It outlines key considerations for South Sudan’s national health authorities when implementing the gradual return of local and international travel operations.

Factors to be considered when resuming travel:

The priority for gradual resumption of travel is given to:

- a. Emergencies.
- b. Humanitarian actions.
- c. Travel of essential personnel such as health providers and diplomatic officers.
- d. Repatriation.
- e. Persons at risk including the elderly and the people with chronic underlying health conditions should avoid travelling to areas with community transmission.
- f. Cargo transport should also be prioritized for essential medical, food and energy supplies.

Epidemiological situation and transmission patterns at origin and destination countries:

COVID-19 epidemiological situation varies among countries, hence; international travel carries different levels of risk of exportation/importation of SARS-CoV-2 virus, depending on the passenger’s country of departure and country of arrival.

The epidemiological situation of COVID-19 in each country is available through WHO Situation

Reports, which follow the transmission scenarios defined in the Interim Guidance of WHO Global surveillance for COVID-19 caused by human infection with COVID-19 virus published on March 20, 2020 in which the following four scenarios are considered:

- No cases: Countries / territories / areas with any reported cases.
- Sporadic cases: Countries/territories/areas with one or more cases, imported or locally detected.
- Clusters: Countries/territories/areas experiencing cases, clustered in time, geographic location and/or by common exposures
- Community transmission: Countries/territories/areas experiencing larger outbreaks of local transmission defined through an assessment of factors including, but not limited to:
 - Large numbers of cases not linkable to transmission chains
 - Large numbers of cases from sentinel laboratory surveillance
 - Multiple unrelated clusters in several areas of the country/territory/area.

Coordination and planning:

The transport sector is central to travel operations, but the involvement of other sectors such as trade, agriculture, tourism and security are essential to capture all the operational aspects associated with the gradual resumption of international travels.



Surveillance and case management capacity:

Active epidemiological surveillance for case detection, case isolation, contact identification and contact follow-up are central to the effective management of the COVID-19 pandemic. Persons who are suspect or confirmed to have COVID-19 and contacts of confirmed cases should not be allowed to travel.

International contact tracing:

When a cluster or chain of transmission involves several countries, international contact tracing can be done in a coordinated and collaborative manner through rapid information sharing via the international network of National "WHO International Health Regulations (IHR)" IHR Focal Points (NFPs).

The NFPs should be accessible at all times and can receive direct support from the regional WHO International Health Regulations (IHR) Contact Points.

Risk communication and community engagement:

It is essential to proactively communicate to the public through traditional media, social media and other channels about the rationale for gradually resuming international travels, the potential risk of travel and the measures required to ensure safe travel for all, including regular updates on changes in international travel to disseminate information and provide advice tailored to subnational level situations. This is essential to build trust in travel advice, increase compliance with health advice and prevent the spread of rumors and false information.

Required Capacity at Points of Entry:

We should strengthen our capacity at Juba International Airport and other Points of Entry (PoE) for the COVID-19 response, especially:

- a. Entry/exit screening
- b. Early detection through active case finding
- c. Isolation and testing of ill passengers
- d. Supply of personal protective equipment (PPEs) at PoE
- e. Cleaning and disinfection
- f. Case management
- g. Identification of contacts for contact-tracing;
- h. Physical distancing and mandatory wearing of masks;
- i. Sharing of emergency phone numbers; and
- j. Risk communication and education on responsible travel behavior.
- k. Adapted procedures for handling baggage, cargo, containers, conveyances, goods and postal parcels should be available and clearly communicated.

General advice for travelers:

- a. Adequate personal and hand hygiene,
- b. Proper respiratory etiquette,
- c. Maintaining physical distance of at least one meter from others
- d. Use of a mask as appropriate.



e. Sick travelers and persons at risk, including elderly travelers and people with serious chronic diseases or underlying health conditions, should, where possible, postpone travelling to and from areas with community transmission.

Laboratory testing and Certification at Points of Entry and Quarantine requirements:

a. Molecular testing for SARS-CoV-2 within 96 hours of sampling- prior to arrival is the current requirement for entry into South Sudan. A hard copy of the PCR result is required from a recognized laboratory.

b. International passengers can either quarantine for 10 days OR be tested on the 7th full day of quarantine from arrival at their cost. Those who test negative with a recommended RT-PCR after day 7 can be discharged from their self- isolation and allowed to continue their local journey within the country without any further restriction. Those choosing not to be tested on or after day 7 may exit quarantine on day 10. Any person exhibiting symptoms at any point in the quarantine period will need to be tested and may not leave before day 10. (N.B. the day of arrival in South Sudan is day zero)

c. International travelers should self-monitor for the potential onset of symptoms on arrival, report symptoms and travel history to local health facilities and follow the national protocols.

Public – Private Partnership on COVID-19:

a. The current capacity of our public health laboratory (PHL) may not meet the increasing demand of the international travelers.

b. Competent private hospitals and clinics have been encouraged to run molecular testing using recommended RT –PCR provided that these private laboratories are working in tandem with the PHL and they have a clear chain of communicating secured data. These private laboratories provide a paid service for travelers requiring PCR certificates to travel. Please see Ministry of Health announcements for the latest list of authorized laboratories.

Guidelines and Surveillance for Local Travelers:

Antigen-detection rapid diagnostic tests (Ag-RDTs) should be used to screen symptomatic local travelers whether using air, river, or land routes as part of community-based surveillance.

The sensitivity (ability to accurately detect those with disease) and specificity (ability to accurately detect those without disease) of WHO-approved Ag-RDTs are >80% and >97%, respectively. Guidance on interpretation of results and recommendations on confirmatory testing is outlined in the Ag-RDT algorithm in the Ag-RDT SOP.

Ag-RDTs that have received WHO Emergency Use Listing (EUL) for detection of SARS-CoV-2 viral antigens will be used when available.

Guidelines on the use of Ag-RDTs (Antigen Rapid Diagnostic Tests) for testing for COVID-19 in South Sudan:

Background

To meet the urgent diagnostics needs of the COVID-19 pandemic, nucleic acid amplification tests (NAATs) were rapidly developed to detect and identify cases. In



January 2020, only 2 African countries (South Africa and Senegal) had the capacity to conduct polymerase-chain reaction (PCR) methods. By March 2020, all African countries could diagnose SARS-CoV-2 via PCR, including South Sudan. Though PCR is the gold standard for SARS-CoV2 detection, there are challenges that make this method difficult to decentralize. PCR requires advanced infrastructure and skilled personnel in addition to being labor intensive and requiring long turnaround times for results leaving most sophisticated labs in capitals and cities. With the advent of antigen rapid diagnostic tests (Ag-RDTs) for COVID-19, more cases can be detected quickly.

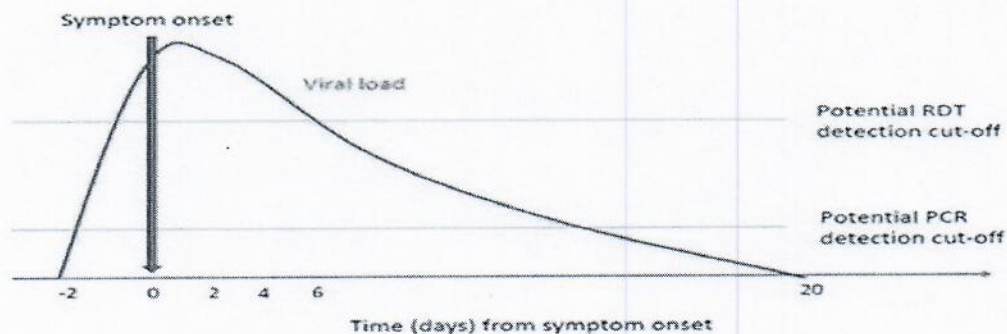
As of December 15, 2020, the World Health Organization (WHO) approved three Ag-RDTs for Emergency Use Listing (EUL) for detection of SARS-CoV-2 viral antigens. One of the approved Ag-RDT assays is produced by SD Biosensor Inc and the other two are produced by Abbott Rapid Diagnostics Jena GmbH.

Available WHO reports¹²³ on the three Ag-RDTs show that they met the following minimal performance requirements compared to NAAT reference assay:

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%)

Given the expected sensitivity of Ag-RDTs, a negative test result does not necessarily rule out infection. Clinical and epidemiologic information should also be considered to guide the implementation of Ag-RDTs. 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 after onset of symptoms (Figure 1).

Who can be detected with an Ag-based RDT?



World Health
Organization

EMERGENCIES

Figure 1. Testing sensitivity profiles for antigen rapid diagnostic (Ag-RDT) and polymerase chain reaction (PCR) tests.

WHO and Africa CDC recommend use of Ag-RDTs for the following scenarios:

¹https://extranet.who.int/pqweb/sites/default/files/documents/EUL_WHOPR_Abbott-PanbioCOVID-19_AgRapidTestDeviceNASAL_EUL-0587-032-00.pdf

²https://extranet.who.int/pqweb/sites/default/files/documents/0564-032-00_PanbioCOVID-19-AgRapidTestDevice.pdf

³https://extranet.who.int/pqweb/sites/default/files/documents/201019_eul_0563_117_00_standard_q_ag_test.pdf



- **Surveillance-** To detect individuals during the infectious phase to reduce the risk of transmission
- **Point of care (PoC) tests-** RDTs are cheaper, have shorter Turn-Around Time (TAT) to detect localized outbreaks, isolate positive cases and stop transmission and help prevent nosocomial spread
- **Patient management** - RDTs have high sensitivity and quick TAT to triage patients and screen health workers

Ag-RDTs are not recommended for use in low prevalence settings⁴. The Ag-RDT does not replace the use of the PCR and should be used in combination where required, depending on the epidemiological situation and clinical history of the individual. **PCR remains the gold standard for testing.**

In South Sudan, only WHO EUL and or US FDA EUA Ag-RDTs are recommended for use and only for the scenarios below. This guidance will evolve as new evidence emerges.

CONTEXT OF Ag-RDT USE IN SOUTH SUDAN

Following the WHO and Africa CDC guidance documents on the use of these diagnostic devices, the Laboratory TWG recommends the WHO EUL and or US FDA Ag-RDTs that have undergone in-country verification and found suitable to be used in specific settings and contexts (Box 1).

Box 1. Selected scenarios for use of Ag-RDTs.

1. Use of Ag-RDTs to screen for COVID-19 in healthcare settings

Ag-RDTs can be used for the testing of health workers for COVID-19 and for testing **patients with symptoms** of COVID-19 presenting in hospitals and other health facilities. A positive RDT test confirms SARS Cov-2 infection. All Ag-RDT negative cases are considered negative; however, if COVID-19-like symptoms are present or persist, a PCR test should be done. Ag-RDTs can also be used to screen for COVID-19 in non-symptomatic patients. If the Ag-RDT result is positive, perform a PCR test for confirmation. If the Ag-RDT is negative, the patient is considered negative. Testing should be prioritized for health workers with 1) signs/symptoms consistent with COVID-19; 2) high-risk exposures to SARS-CoV-2; or 3) SARS-CoV-2 infection diagnosis to determine when they are no longer infectious.

2. Use of Ag-RDTs to screen for COVID-19 among 1) contacts of a PCR-confirmed case; 2) COVID-19 alerts; 3) sentinel sites; and 4) points of entry (POE)

Ag-RDTs can be used for the testing of contacts of a PCR-confirmed COVID-19 case, suspect cases identified via a COVID-19 alert, suspect cases identified at sentinel site locations, and **symptomatic** persons presenting at POEs. Any person in these scenarios who tests positive on using Ag-RDT is considered confirmed for COVID-19 and case management protocols should be followed. If Ag-RDT is negative, the person is considered negative. Contacts of a case should complete the stipulated quarantine period regardless of presence of symptoms **or** diagnostic outcome (Ag-RDT or PCR).

3. Use of Ag-RDTs to screen for COVID-19 in closed, congregate, and outbreak settings

Ag-RDTs can be used as a screening test for refugee camps, POC sites, correctional/prison facilities, and other similar closed settings. In these closed settings, the first case in each setting that is positive with Ag-RDT should be retested with PCR for confirmation. For South Sudan this can be done because the 10 camps in South Sudan have operational GXP testing facilities. Once one positive test has been confirmed by PCR, all subsequent Ag-RDT positive results are considered as confirmed and do not require re-testing. This should be the case, until there is a 14-day (or more) gap between the recording of the last Ag-RDT positive case and a new case. All RDT-negative cases are considered truly negative if no SARS-CoV-2 symptoms persist.

⁴ Low prevalence is defined as a 7-day moving average yield of <5%.



Interpretation of RDT results

The performance and interpretation of Ag-RDT results may differ in varying prevalence settings. In settings with high prevalence⁵, for patients who test RDT negative and have COVID-19-like signs and symptoms and/or are close contacts of a case, testing should be repeated with PCR due to increased risk of false negatives. For patients with a positive RDT in a low prevalence setting, confirmation should be done by PCR due to the increased risk of false positives (Figure 2).

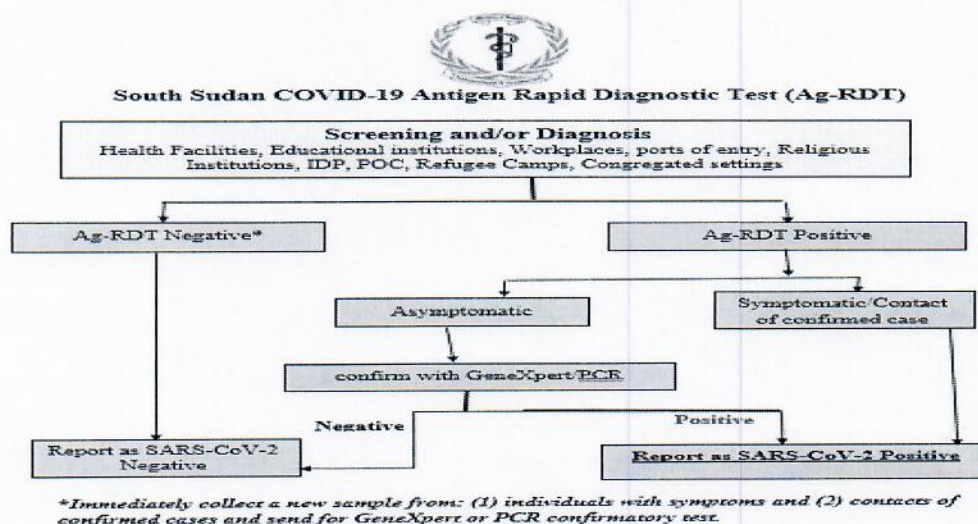


Figure 2. Algorithm to guide the use of Ag-RDTs and indications for confirmatory testing. This algorithm should be adapted to national, state, and county conditions.

Data and documentation requirements

Diligent collection of data using PHEOC-approved **case investigation and contact listing forms** for integration into the national database will be required. Ag-RDT results data are part of the laboratory data the country relies on for important decision-making related to the pandemic and provide vital guidance for control activities. Ag-RDT results should be reported following national guidelines and considering the existing surveillance data reporting protocols. All users of Ag-RDTs are expected to use the standard CIF and contact listing form. This requirement enables PHEOC to accurately determine the burden of infection in key groups, improve decision-making, and better prevent or mitigate spread of disease.

Safety/protective considerations

The safety guidelines for collecting samples for testing and manufacturer's instructions should be followed. Assays should be performed on a large paper towel (or equivalent) in a well-ventilated area free of clutter using the appropriate personal protective equipment (PPE): disposable gloves, full-length laboratory coats/gowns, eye and/or facial protection, and surgical mask. Handle laboratory waste from testing patients as all other biohazardous waste in the laboratory. Disinfect general surfaces per standard laboratory guidelines.

Orientation for users in the field

⁵ High prevalence is defined as a 7-day moving average yield of $\geq 5\%$.



Sample collection is one of the most critical factors affecting performance of Ag-RDTs. Instructions for use should be carefully followed, and any staff collecting samples should be trained in the methodology. All users of Ag-RDTs at all sites should undergo appropriate training and orientation sessions to assure correct procedures are followed. Implementing partners should assure that appropriate job aids, algorithms, and other tools necessary for implementation.

Supply chain and logistics

Ag-RDTs can help fill a gap in the low rates of state-based testing, particularly at the GXP sites. However, the country has a limited supply of Ag-RDTs, and successful delivery of this supply predicts the ability to order and acquire more. Systems to document and track chain of custody for RDTs sent to states and specific facilities will be important to help us track uptake and appropriate usage, calculate yields for those testing positive, and monitor implementation and reporting. Adherence to shipping, handling, uptake, and use of delivered Ag-RDTs should follow existing National Public Health Laboratory (NPHL), WHO, and implementing partner guidelines.

NOTE: To safeguard health workers, respiratory sample collection for any test from patients with suspected COVID-19 requires that operators wear gloves, gown, mask and face shield or goggles.



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