SARS-CoV-2 antigen-detecting rapid diagnostic tests

AN IMPLEMENTATION GUIDE

World Health Organization

FIND
Because diagnosis matters

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SARS-CoV-2 antigen-detecting rapid diagnostic tests: an implementation guide

ISBN 978-92-4-001774-0 (electronic version)
ISBN 978-92-4-001775-7 (print version)

Contents

Acknowledgments

This SARS-CoV-2 antigen-detecting rapid diagnostic test implementation guide is a product of collaboration between the World Health Organization (WHO) and the Foundation for Innovative New Diagnostics (FIND), with support from the Access to COVID-19 Tools (ACT) Accelerator Country Preparedness Working Group; African Society for Laboratory Medicine (ASLM); Centers for Disease Control and Prevention (CDC); Clinton Health Access Initiative (CHAI); The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund); Médecins Sans Frontières; and PATH.

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Abbreviations

Ab	antibody
Ab-RDT	antibody-detecting rapid diagnostic test
Ag	antigen
Ag-RDT	antigen-detecting rapid diagnostic test
COVID-19	coronavirus disease 19
EUL	emergency use listing
HIS	health information system
LIMS/LIS	laboratory information management system
LMIC	low- and middle-income country
M&E	monitoring and evaluation
NAAT	nucleic acid amplification test
NPV	negative predictive value
PPE	personal protective equipment
PPV	positive predictive value
PT	proficiency testing
QA	quality assurance
QC	quality control
rRT-PCR	real-time reverse transcription polymerase chain reaction
RDT	rapid diagnostic test
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2

1

OVERVIEW OF IMPLEMENTATION GUIDE

1 OVERVIEW OF IMPLEMENTATION GUIDE

This guide provides an overview of the major elements that must be considered before, during and after the implementation of antigen-detecting rapid diagnostic tests (Ag-RDTs) for SARS-CoV-2, the virus that causes COVID-19. This guide is complementary to policy guidance issued by the World Health Organization (WHO). Details on the global policy for COVID-19 testing can be found in the WHO publication *Diagnostic testing for SARS-CoV-2 (1)*[1].

This guide borrows heavily from the experience and lessons learned from other disease control programmes, such as HIV and malaria, that have implemented rapid diagnostic tests (RDTs) as part of their diagnostic algorithms over the past two decades *(2)*. It also emphasizes the importance of using existing content that has been developed to support implementation of other components of COVID-19 testing, such as sample collection and the use of personal protective equipment (PPE). The guide will be updated once Ag-RDTs are rolled out and use is scaled up, generating further evidence on how to optimize their implementation in different settings.

This guide may appeal to a range of audiences including:

- ministries of health (national, provincial, regional and district COVID-19 assigned personnel and Ag-RDT end-users) with an emphasis on resource-limited settings;
- donors considering supporting diagnostic testing services with Ag-RDTs for COVID-19;
- public and private sector organizations with an interest in implementing SARS-CoV-2 Ag-RDT services;
- health care providers involved in the diagnosis and management of COVID-19 cases; and
- community-based and civil society organizations with experience working on health, especially organizations familiar with similar testing campaigns for other disease programmes like HIV and malaria.

Malaria and HIV programmes scaled up the use of RDTs over a number of years, armed with extensive knowledge of test performance, operational quality assurance (QA) systems, and awareness campaigns targeting patients and providers. By contrast, to combat the COVID-19 pandemic, SARS-CoV-2 Ag-RDTs need to be rolled out urgently over weeks and months, potentially across the full spectrum of health care and community settings and health worker cadres. Their use could be multipronged, as Ag-RDTs can support individual case management, contact tracing, surveillance and outbreak investigations. To achieve this safely and efficiently, a basic understanding of how Ag-RDTs work and their advantages and disadvantages must be combined with strict protocols for their use, QA and clear communication. When using SARS-CoV-2 Ag-RDTs, specific personal and environmental precautions are needed to protect against transmission of respiratory pathogens. Additionally, the impact of these collective efforts should be monitored to determine the effects on patients and public health.

To this end, this guide is designed around the **key requirements for the effective implementation of Ag-RDT diagnostic testing services**.

[1] Other technical guidance for COVID-19 can be found at: *https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications*.

2

CONTEXT OF THE CORONAVIRUS DISEASE (COVID-19) PANDEMIC

2 CONTEXT OF THE CORONAVIRUS DISEASE (COVID-19) PANDEMIC

Brief history of the pandemic

On 31 December 2019, WHO became aware of a cluster of pneumonia of unknown etiology reported in Wuhan, People's Republic of China. On 30 January, WHO declared a Public Health Emergency of International Concern. The virus was initially named 2019 novel coronavirus (2019-nCoV) *(1)*. However, on 11 February 2020, the new coronavirus was given the official name severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and the disease caused by the virus was named coronavirus disease 2019 (COVID-19). SARS-CoV-2 spread rapidly around the world and WHO made the assessment it could be characterized as a pandemic on 11 March 2020 *(3)*. The clinical presentation of SARS-CoV-2 infection can range from asymptomatic infection to severe disease. Mortality rates have differed by country to date *(1)*.

Central role of testing in the response

Testing is part of the first line of defence against COVID-19, enabling early identification and isolation of cases to slow transmission, provision of targeted care to those affected, and protection of health system operations. Laboratory tests for COVID-19 based on nucleic acid amplification techniques (NAAT) were rapidly developed in the early days and weeks of the pandemic, but such tests typically require sophisticated laboratory infrastructure and skilled staff. To date, hundreds of millions of COVID-19 tests have been performed globally, but the demand for timely, accurate testing continues to outstrip supply.

WHO recommends that persons meeting the suspected COVID-19 case definition *(4)* be tested immediately in order to confirm or rule out infection with SARS-CoV-2. In contexts where testing is not possible, a probable case of COVID-19 may instead be reported based on certain epidemiological criteria and clinical symptoms or signs *(4)*. It is expected that Ag-RDTs will greatly expand access to testing, enabling the most accurate estimates of disease burden and targeting of control measures and treatments.

Urgent needs in the pandemic response

Controlling COVID-19 requires testing services to be scaled up and access to testing improved in decentralized settings. The limited coverage of laboratory services and long turnaround times has meant that NAAT (such as real-time reverse transcription polymerase chain reaction [rRT-PCR]) capacity has been insufficient to meet demand in many countries, particularly in low- and middle-income countries (LMICs). In LMICs, these limitations have resulted in testing rates that are around 10 times lower than in high-income countries *(5)*.

Timely, detailed COVID-19 testing and surveillance data are vital to the COVID-19 public health response. As noted by WHO, "*It is essential to have real-time, accurate data on the testing of suspected cases, the nature and isolation status of all confirmed cases, the number of contacts per case and completeness of tracing, and the dynamic capacity of health systems to deal with COVID-19 cases*" *(6)*. Countries therefore need to prioritize making real-time data available.

3

HOW COVID-19 IS DIAGNOSED

3 HOW COVID-19 IS DIAGNOSED

Molecular testing

WHO recommends that, wherever possible, suspected cases with active SARS-CoV-2 infection be tested using molecular NAAT methods, such as rRT-PCR *(1)*, which detect the presence of viral RNA in patient samples from the respiratory tract but also in oral fluid, saliva and stool. The optimal specimen for NAAT methods depends on the clinical presentation and time since symptom onset. Further information on specimen types for molecular testing can be found in the document *Diagnostic testing for SARS-CoV-2 (1)*.

Given the risk of potential exposure to virus during sample collection and when handling respiratory samples, technicians must follow recommended biosafety guidance and adhere strictly to infection prevention and control procedures (for further information see WHO's *Laboratory biosafety guidance related to COVID-19 (7)*).

During the COVID-19 pandemic, countries have had to rapidly launch and scale up laboratory testing capacity, which has presented a number of challenges. While an essential part of the testing response to COVID-19, NAATs typically require well-resourced laboratory facilities, multiple reagents, sample referral systems and skilled personnel. Many settings lack the sophisticated infrastructure required to provide widespread molecular testing for COVID-19, particularly in LMICs. Long transport distances for referral and slow turnaround times can limit the clinical and public health impact of molecular testing for COVID-19, where timely detection is critical. Supply shortages of essential and compatible reagents are further complicating the scale-up of molecular testing for COVID-19 in certain settings. The high cost of molecular testing also limits the testing coverage that can be achieved within countries' diagnostic funding envelopes. Similarly, access and price remain substantial barriers to point-of-care molecular testing in many settings.

Rapid diagnostic testing

RDTs are easy-to-use, rapid tests that can be used at or near the point of care, without the need for laboratory infrastructure or expensive equipment. There are two types of SARS-CoV-2 RDTs: antigen (Ag) tests that directly detect the SARS-CoV-2 virus antigen(s), and antibody (Ab) tests that detect one or more types of antibodies produced by the host immune response against the virus.

Antigen-detecting RDTs

Ag-RDTs directly detect SARS-CoV-2 antigens, most often nucleocapsid, produced by the replicating virus in respiratory secretions. Therefore, like molecular testing, Ag-RDTs are useful for detecting active COVID-19 infection. Most SARS-CoV-2 Ag-RDTs require nasopharyngeal samples, but may be suitable for use with other sample types once more data are available. The accuracy of Ag-RDTs depends on several factors, including the time from onset of infection, the concentration of virus in the specimen, the quality and processing of the specimen collected from a person, and the precise formulation of the reagents in the test kits.

Ag-RDTs for COVID-19 will most often be positive when viral loads are highest and patients are most infectious – typically 1–3 days prior to the onset of symptoms and during the first 5–7 days after the onset of symptoms – and will become negative as the patient clears the infection and recovers *(8)*. When viral loads fall below the test's limit of detection (typically around PCR cycle threshold values[2] of <30–35), Ag-RDTs may return false negative results. Consequently, a negative Ag-RDT result cannot completely exclude an active COVID-19 infection. In this situation, repeat testing or preferably confirmatory testing using NAAT should be performed whenever possible, particularly in symptomatic patients. Furthermore, negative Ag-RDT results should not be the basis for removing symptomatic or asymptomatic contacts of cases from quarantine requirements. Nonetheless, positive Ag-RDT results in asymptomatic contacts can be useful for rapidly broadening contact-tracing efforts.

For Ag-RDTs that meet the minimum performance criteria set by WHO (defined in Section 4), positive results indicate active SARS-CoV-2 infection when used in settings where SARS-CoV-2 is common. Further information on how to correctly interpret test results can be found in Section 5 of this guide.

Antibody RDTs

Ab-RDTs detect the body's immune response to the virus in the form of antibodies. These tests are quite accurate around 15–21 days post infection *(9)*.

As understanding of antibody responses to SARS-CoV-2 is still emerging, WHO recommends that antibody detection tests not be used for determining active infections in clinical care or for contact-tracing purposes. Interpretation of Ab-RDT results should be done by an expert and is dependent on several factors, including the timing of the disease, clinical morbidity, the epidemiology and prevalence within the setting, the type of test used, the validation method, and the reliability of the results *(1)*.

The clinical significance of a positive antibody test is still under investigation. It should be noted that the presence of antibodies that bind to SARS-CoV-2 does not guarantee that they are neutralizing antibodies or that they offer protective immunity.

However, antibody testing may be useful for serosurveillance studies to support the investigation of an ongoing outbreak and to support the retrospective assessment of the attack rate or size of an outbreak.

This guide refers only to **antigen-detecting RDTs**.

[2] The cycle threshold (Ct) value is defined as the number of cycles of amplification (using rRT-PCR) required for the fluorescence of a PCR product (i.e., the target/amplicon) to be detected, crossing a threshold that is above the background signal (a low-level signal that is present in the assay regardless of whether the target is present).

Table 1. Advantages and disadvantages of testing methods for SARS-CoV-2

TEST TYPE	ADVANTAGES	DISADVANTAGES
Nucleic acid amplification testing (NAAT)	• Detects active SARS-CoV-2 infection • High sensitivity and specificity	• Turnaround time of hours to days • Labour intensive • Requires laboratory infrastructure and skilled personnel • More expensive than RDTs
Rapid diagnostic tests: Antigen-detecting tests	• Detects active SARS-CoV-2 infection • Can be used at the point of care (outside laboratories) • Easy to perform • Quick results (typically under 30 minutes) enabling rapid implementation of infection control measures, including contact tracing • Less expensive than NAAT, e.g., RT-PCR tests	• Variable sensitivity and specificity, generally lower than NAAT • Lower sensitivity means negative predictive value is lower than for NAAT, especially in settings with high prevalence of SARS-CoV-2 • Confirmatory NAAT testing of RDT positives is advised in all low-prevalence settings and for RDT negatives in high-prevalence settings. • Negative Ag-RDT results cannot be used to remove a contact from quarantine
Rapid diagnostic tests: Antibody-detecting tests	• Ab-RDTs can be used to detect previous infection with SARS-CoV-2 • Can be used at the point of care (outside laboratories) or in higher throughput formats in laboratories • Easy to perform • Quick results (typically under 30 minutes for point-of-care testing) • Less expensive than NAAT, e.g., RT-PCR tests	• Clinical significance of a positive Ab-RDT result is still under investigation • Positive Ab-RDT results do not guarantee presence of neutralizing antibodies or protective immunity • Ab-RDTs should not be used for determining active infections in clinical care or for contact-tracing purposes • Interpretation of Ab-RDT results depends on the timing of the disease, clinical morbidity, the epidemiology and prevalence within the setting, the type of test used, the validation method, and the reliability of the results

4

ROLE OF AG-RDTs AS PART OF A COVID-19 DIAGNOSTIC TESTING STRATEGY

4 ROLE OF AG-RDTs AS PART OF A COVID-19 DIAGNOSTIC TESTING STRATEGY

A combination of different test types will be needed to expand testing capacity to meet demand for COVID-19 in all settings. SARS-CoV-2 Ag-RDTs can be incorporated into testing strategies where NAAT methods are not available or turnaround time is too long to inform clinical decision-making and public health measures such as contact tracing. Prolonged turnaround times may be secondary to multiple factors, including limited human or financial resources, sample transport requirements, and reagent shortages. Ag-RDTs can both fill gaps in access to testing and alleviate pressure on laboratories performing NAAT, thereby reducing delays in diagnosis and optimizing use of available tools.

There is currently little programmatic experience using Ag-RDTs for SARS-CoV-2; therefore, guidance will be updated as new information becomes available from early-adopter countries. Additional and/or modified use cases may emerge as more data on Ag-RDT performance becomes available through roll-out and as next-generation RDTs become available.

Recommendations for the use of SARS-CoV-2 Ag-RDTs

WHO has issued interim guidance on the use of SARS-CoV-2 Ag-RDTs in the diagnosis of COVID-19, summarized below. The full guidance can be found in WHO's *Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays (8).*

General recommendations for the use of SARS-CoV-2 Ag-RDTs (8):

1. Only Ag-RDTs that meet recommended performance criteria[3] should be considered for use only in areas where NAAT is unavailable or where the health system may be overburdened, leading to prolonged NAAT turnaround times (>48–72 hours).
2. Testing with Ag-RDTs should be conducted by trained operators in strict accordance with the manufacturers' instructions. For best results, tests should be performed within the first 5–7 days following the onset of symptoms.

Table 2 outlines the use cases currently recommended for SARS-CoV-2 Ag-RDTs based on current evidence.

[3] ≥80% sensitivity and ≥97% specificity compared to an approved NAAT.

Table 2. Use cases for SARS-CoV-2 Ag-RDTs

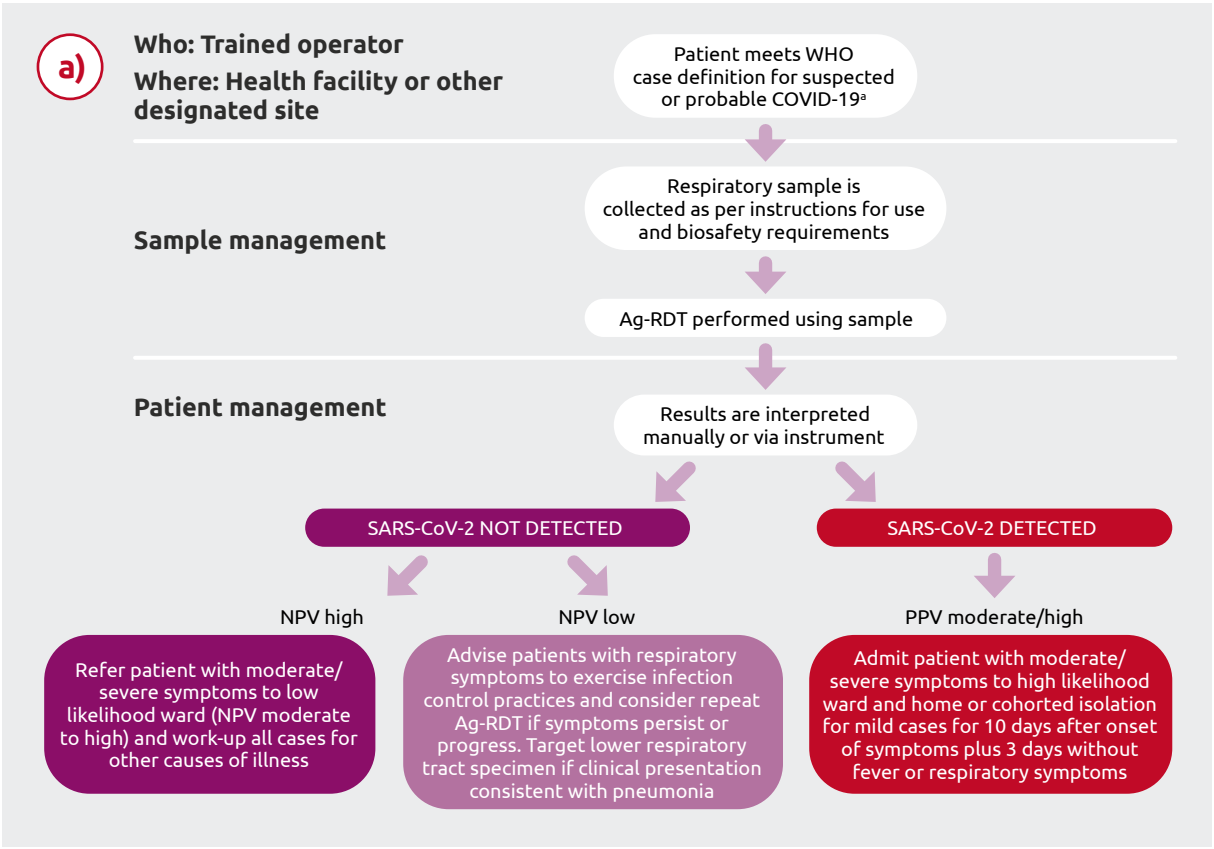
INDICATION FOR TESTING	POPULATION RECOMMENDED FOR SCREENING
Outbreak investigation/ contact tracing	To respond to suspected outbreaks of COVID-19 in remote settings, institutions and semi-closed communities where NAAT is not immediately available.
	To support outbreak investigations (e.g., in closed or semi-closed groups like schools, care homes, workplaces etc.). Where COVID-19 outbreaks have been confirmed, Ag-RDTs could be used to screen at-risk individuals and rapidly isolate positive cases.
Monitoring trends in disease incidence	To monitor trends in COVID-19 rates in communities, and particularly among essential workers and health workers during outbreaks or in regions of widespread community transmission where the positive predictive value (PPV) and negative predictive value (NPV) of an Ag-RDT result is sufficient to enable effective infection control.
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.
Testing of asymptomatic contacts of cases	Despite the second general recommendation, testing of asymptomatic contacts of cases may be considered even if the Ag-RDT is not specifically authorized for this use, as asymptomatic cases have viral loads similar to those of symptomatic cases. However, in this situation, a negative Ag-RDT result should be considered presumptive and is not sufficient to remove a contact from quarantine requirements. Positive Ag-RDT results, however, can be useful for targeting isolation procedures and broadening contact-tracing efforts.

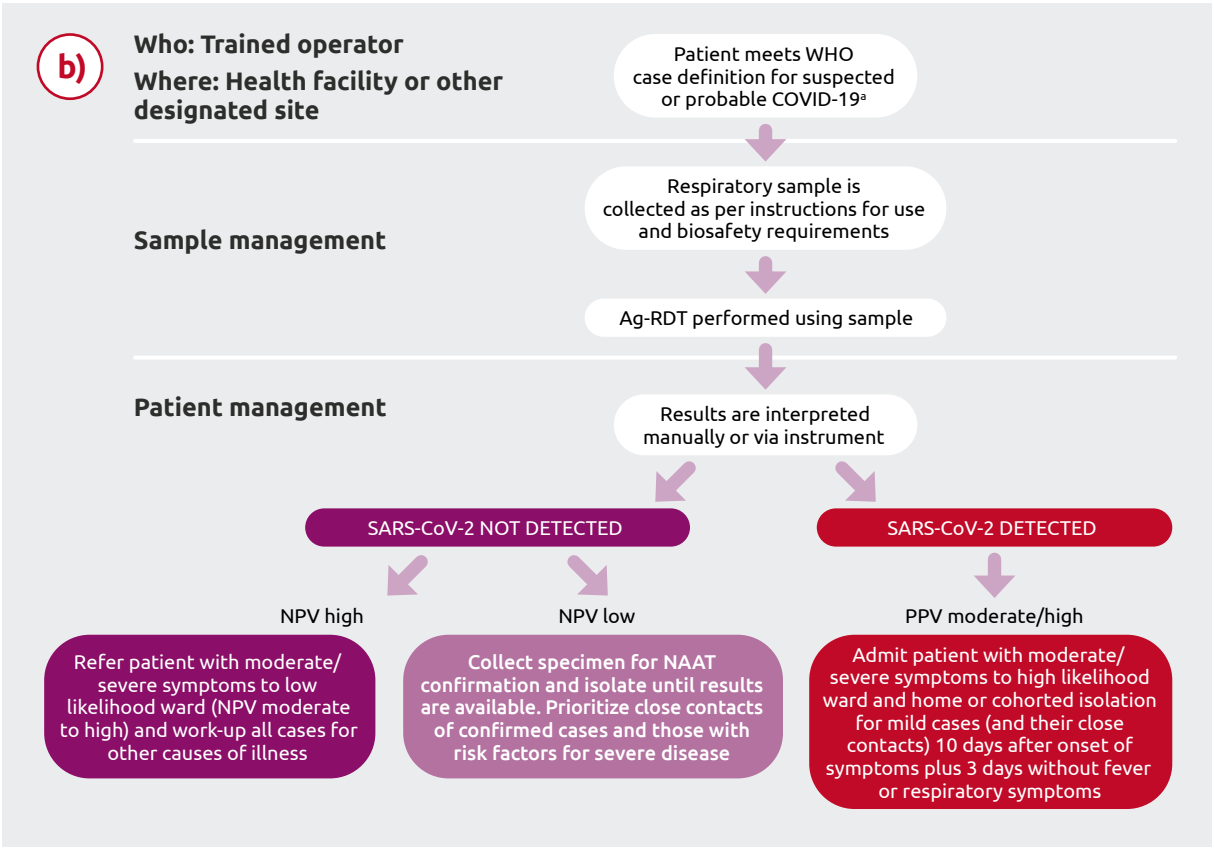
For initial introduction of Ag-RDTs, implementers should consider selecting some settings where confirmatory testing by NAAT (e.g., rRT-PCR) is available. This will enable operators to gain confidence in the tests, confirm performance of the selected RDT, and troubleshoot any implementation issues encountered.

In situations where confirmatory NAAT is not feasible, implementers should be careful to monitor for any indication that results may be incorrect. This should include routine monitoring of quality indicators and matching of test results to clinical history and epidemiological context.

Fig. 1 shows the proposed process for using Ag-RDTs for COVID-19 case management where there is widespread community transmission and NAAT is not available or limited in capacity.

Fig. 1. Flowchart demonstrating the potential use of Ag-RDTs (that meet minimum performance criteria) in settings of widespread community transmission and where there is a) no NAAT capacity or b) limited NAAT capacity





[a] For the latest WHO case definition please refer to the technical guidance document on *https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications?publicationtypes=df113943-c6f4-42a5-914f-0a0736769008*

Ag-RDTs for COVID-19 should not be used in the following settings, based on currently available information:

The use of Ag-RDTs is not recommended in settings or populations with low expected prevalence of disease (e.g., screening at points of entry, prior to travel, elective surgery), where confirmatory testing by NAAT is not readily available. In such settings, the rate of false positives compared to true positive results will be high. RDT testing in low-prevalence settings without NAAT confirmation will not be advisable until there are significantly more data from high-quality studies confirming very high specificity (>99%) of one or more commercialized Ag-RDT test kits.

Specific examples of settings where Ag-RDTs **should not be used** include:

- in individuals without symptoms, unless the person is a contact of a confirmed case;
- where there are zero or only sporadic cases;
- where appropriate biosafety and infection prevention and control measures are limited or lacking;
- where management of the patient and/or use of COVID-19 countermeasures do not change based on the result of the test;
- for airport or border screening at points of entry or prior to travel (unless all Ag-RDT positive results can be confirmed by NAAT); and
- in screening prior to elective surgery or blood donation.

The WHO guidance in this section is based on existing information on the performance of SARS-CoV-2 Ag-RDTs. Many settings may be using local validation to support other use of Ag-RDTs, for example, using non-standard specimens. Ongoing studies will provide more rigorous data to inform further guidance on the use of SARS-CoV-2 Ag-RDTs.

5

HOW SARS-CoV-2 AG-RDTs WORK

5 HOW SARS-CoV-2 AG-RDTs WORK

Structure of Ag-RDTs

Ag-RDTs detect antigens from clinical specimens using a simple-to-use immunochromatographic (lateral flow) test format, as commonly used for HIV and malaria rapid testing *(8)*.

RDTs are typically a nitrocellulose strip enclosed in a plastic cassette with a sample well. When the infected patient's sample is combined with the test buffer and added to the sample well of the test strip, target antigens in the mixture bind to labelled antibodies and migrate together; they are subsequently captured by an antibody bound to the test line, triggering a detectable colour change.

Depending on the test (and the antibody labels used), the colour change can be read by the operator with or without the aid of a reader instrument *(8)*. RDTs for COVID-19 can produce results in around 10–30 minutes versus the many hours required for most NAATs *(8)*.

Interpreting Ag-RDT performance

Ag-RDT performance is determined by the sensitivity and specificity of the test to detect a SARS-CoV-2 infection compared to a NAAT reference standard (generally rRT-PCR).

Sensitivity is the percentage of cases positive by a NAAT reference standard that are detected as positive by the Ag-RDT under evaluation.

$$\text{Sensitivity is calculated as: } \frac{\textit{(true positives)}}{\textit{(true positives + false negatives)}} \textit{ x 100}$$

Specificity is the percentage of cases negative by a NAAT reference standard that are detected as negative by the Ag-RDT under evaluation.

$$\text{Specificity is calculated as: } \frac{\textit{(true negatives)}}{\textit{(true negatives + false positives)}} \textit{ x 100}$$

The prevalence of disease in the community being tested strongly affects the test's predictive value in terms of positive predictive value (PPV) and negative predictive value (NPV). PPV is the probability that a person with a positive test result truly has the disease. NPV is the probability that a person with a negative test result truly does not have the disease. The prevalence of disease should be estimated based on surveillance to determine the positive and negative predictive values for Ag-RDTs in order to enable optimal interpretation of the results. The following formulae show how PPV and NPV can be calculated.

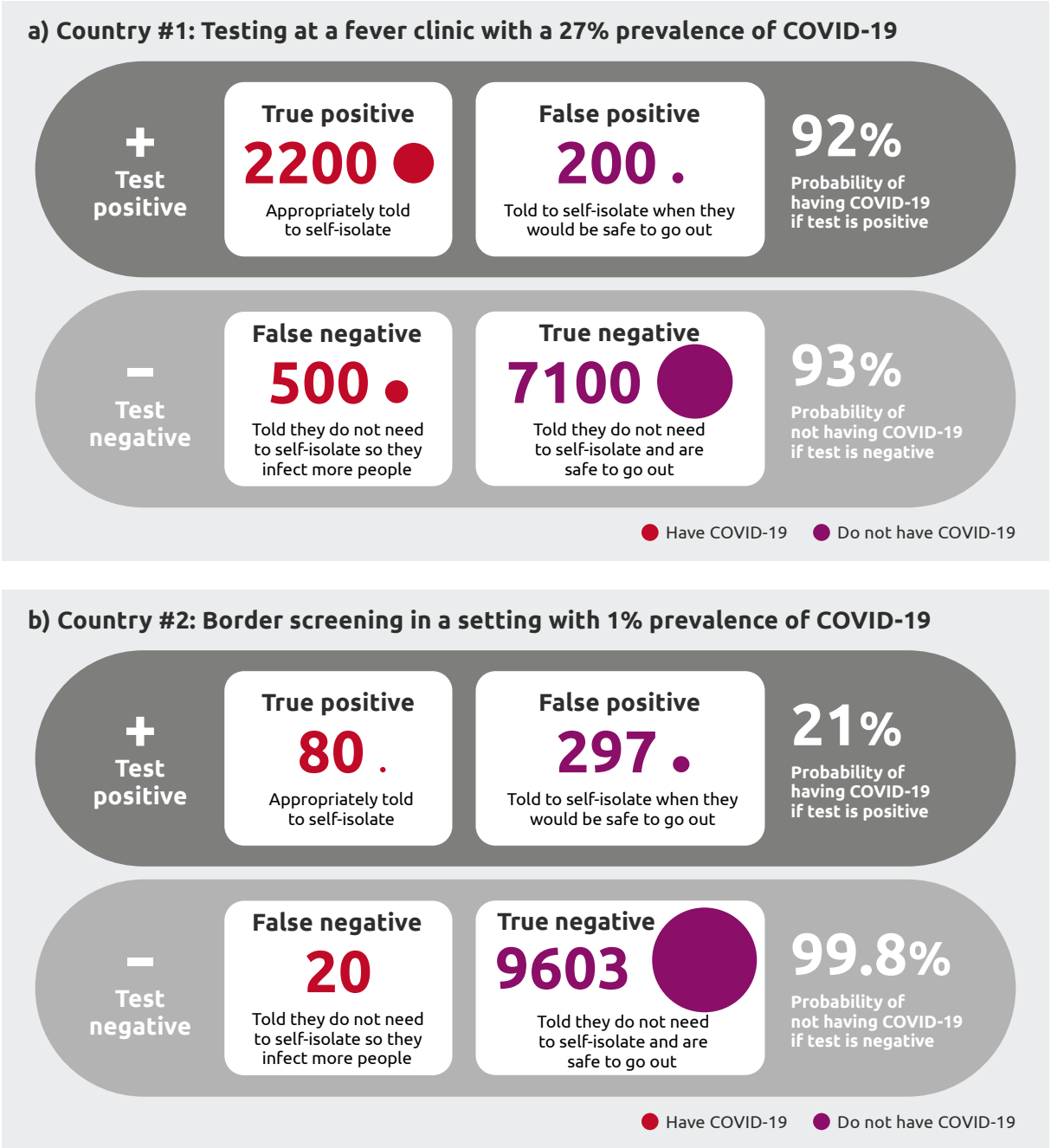
$$\textbf{PPV} \text{ is calculated as: } \frac{\textit{(true positives)}}{\textit{(true positives + false positives)}} \textit{ x 100}$$

$$\textbf{NPV} \text{ is calculated as: } \frac{\textit{(true negatives)}}{\textit{(true negatives + false negatives)}} \textit{ x 100}$$

Consequently, the clinical value of a positive or negative Ag-RDT result will depend on what action is taken on the basis of the test result when interpreted in the context of local prevalence and the PPV and NPV. This is particularly important given the dynamic and heterogeneous epidemiology of SARS-CoV-2. An important point is that as prevalence decreases, so does PPV, meaning that the probability that a positive result is a true positive is reduced in low-prevalence settings; therefore, confirmatory testing is strongly recommended. Conversely, in low-prevalence settings, the NPV is high and thus there is a very high probability that patients who test negative do not have COVID-19.

The real-world examples in Fig. 2 show how the predictive value of an Ag-RDT with the minimum recommended 80% sensitivity and 97% specificity can vary based on the prevalence of COVID-19.

Fig. 2. Predictive value of Ag-RDT with 80% sensitivity and 97% specificity in a) a fever clinic with a 27% prevalence of COVID-19 and b) at border screening with a 1% prevalence of COVID-19, in a population of 10 000 people



Further information of how positive and negative predictive values can affect the interpretation of Ag-RDT test results can be found in the Annex of *Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays (8)*.

Ag-RDT performance expectations and characteristics

A number of SARS-CoV-2 Ag-RDTs are in development or have recently been commercialized. The FIND SARS-CoV-2 diagnostic pipeline tracker lists SARS-CoV-2 Ag-RDTs that have been commercialized or are in development: *https://www.finddx.org/covid-19/pipeline*.

WHO also assesses and lists products through a SARS-CoV-2 in vitro diagnostic Emergency Use Listing (EUL) procedure: https://extranet.who.int/pqweb/sites/default/files/documents/201002_eul_sars_cov2_product_list.pdf.

Evidence on the performance of these RDTs is limited but growing. Available independent data demonstrate heterogeneous performance compared to NAAT in samples from the upper respiratory tract (sensitivity ranging from 0% to 94% for Ag-RDTs). However, almost all of these Ag-RDTs have shown high specificity (>97%), and the performance of some products exceeds minimum performance requirements in patient samples with higher viral loads ($\geq 10^6$ genomic virus copies/mL or cycle threshold values ≤25–30).

6

KEY IMPLEMENTATION CONSIDERATIONS

6 KEY IMPLEMENTATION CONSIDERATIONS

Safe and effective implementation of SARS-CoV-2 Ag-RDT testing services involves several critical elements being in place (Fig. 3). The following section outlines core areas of work and highlights specific activities that represent minimum critical steps. A national-level SARS-CoV-2 Ag-RDT implementation checklist is included in Annex 1 and serves as a practical 'aide-mémoire' for implementers.

Fig. 3. Critical elements required for the safe and effective implementation of SARS-CoV-2 Ag-RDTs

Integrating a SARS-CoV-2 Ag-RDT testing strategy into the national response plan

WHO recommendations should be used to guide development of a national SARS-CoV-2 testing strategy that includes Ag-RDTs, considering the local context. Early engagement with regulatory authorities or establishment of some form of authorization for use is essential to expedite product registration and ensure that Ag-RDT policies can be legally implemented. Additionally, the following key components should be addressed when developing a national testing strategy that includes Ag-RDTs.

Health facility and laboratory capacity mapping

The incorporation of SARS-CoV-2 Ag-RDTs into the national testing strategy should be based on health facility and laboratory capacity mapping to identify the locations most likely to benefit from a high-performing Ag-RDT, including:

- areas not served by NAAT and where turnaround times are particularly prolonged due to the infeasibility of shipping samples or overloading of available infrastructure and personnel;
- areas with a known or estimated high burden of disease, especially in closed or semi-closed communities;
- areas with limited infrastructure, for example, locations without electricity; in these situations, Ag-RDTs that are stable at ambient temperatures and can be read visually would be the only viable option;
- areas where non-facility-based testing is considered essential to improve access to testing, e.g., contact tracing, testing in the community and in other settings;
- areas where turnaround times fall outside the 48-hour window ideally needed for clinical utility of test results.

Epidemiological and environmental setting

Clear use cases and roles should be defined for testing using Ag-RDTs and NAAT. Resources in many settings may be limited, and target use cases and patient populations may be prioritized to achieve the greatest impact on epidemic control. Planners should consider which of the Ag-RDT use cases are of the highest priority based on the current epidemiological setting.

Additional parameters that could influence the impact of testing on epidemic control in each setting include:

- current mitigation strategies and public adherence to policies;
- range of potential policy responses (e.g., public health and social measures, school openings, etc.);
- operational feasibility of certain testing options (e.g., contact tracing); and
- enabling environment for testing (e.g., public trust).

Development of an algorithm for assessment, diagnosis and management of suspected COVID-19 cases

A simple algorithm to guide the assessment, diagnosis and management of suspected COVID-19 cases with either a positive or negative test result should be developed. Overall planning at the central level should be integrated with the available national strategic plans for the COVID-19 response and specifically NAAT testing for COVID-19, which is discussed in the WHO guides, *Diagnostic testing for SARS-CoV-2 (1)* and *Laboratory testing strategy recommendations for COVID-19 (10)*.

Site-readiness

Once districts and health facilities have been selected based on service mapping and disease prevalence, the next step should be to conduct a site-level readiness survey to verify information such as:

- availability of health care workers;
- availability of power supply for charging (if using Ag-RDTs that require a device for reading the result) and storage for tests (if they need to be refrigerated);
- stock monitoring capacity; and
- safety and waste management measures.

Some groups have developed 'readiness' checklists for facilities to support implementation at health facilities (see *WHO/FIND SARS-CoV-2 Ag-RDT Training Materials).*

Approaches to incorporate SARS-CoV-2 Ag-RDTs into a national testing strategy may require adaptation as the pandemic unfolds and further information becomes available.

RDT procurement: selecting the right product

Following the development of a national testing strategy for Ag-RDTs, the next step is to select a good-quality product based on specifications such as performance, thermal stability, cost, intended use and suitability. These factors need to be considered carefully, even when Ag-RDTs are donated from manufacturers, philanthropic organizations or national governments. The WHO-led Diagnostics Consortium for COVID-19[4] has developed a SARS-CoV-2 Ag-RDT product selection tool that can be used to guide product selection. This section describes the key factors to consider when developing a shortlist of Ag-RDT candidates.

Test performance and quality of available data

Data on the performance of Ag-RDTs should be carefully reviewed before procurement is initiated. Given the relatively low prevalence of active SARS-CoV-2 infections even in settings with community transmission, WHO recommends high specificity (minimum ≥97% and ideally >99%) to avoid many false positive results. Ag-RDT tests should have a minimum sensitivity of 80%. Sensitivity varies based on patient-specific factors, such as the degree of illness and days since symptom onset, as well as product quality.

The source of data should be considered. Data from independent studies without corporate sponsorship have particular value if the studies are of high quality, as determined by quality assessment tools such as *QUADAS-2*. Features of the study design can be used to assess study quality, for example, the reference standard used, the type of specimen collected, specimen blinding, the time between sample collection and test, the number of days since symptom onset, and the number and selection of participants. Systematic reviews of diagnostic test accuracy are a good resource for comparing the reported test performance and quality of various studies.

Manufacturing quality and regulatory status

Tests should be procured from manufacturers who work under a validated quality management system and with at least local regulatory approval or right of free sale granted by the country of manufacture. As with all in vitro diagnostics intended for clinical use, Ag-RDTs require rigorous and transparent regulatory review. At the time of procurement, the Ag-RDT should be approved or authorized by the national regulatory body and ideally included in the *Emergency Use List by WHO* or another assessment authority.[5]

Manufacturing capacity and further evidence of quality

Procurers need to consider the manufacturing capacity and record of the companies offering SARS-CoV-2 Ag-RDTs. Procurers should consider the range of other products offered by the company, particularly whether the company has any other lateral flow tests, what regulatory approvals it has for non-emergency diagnostic products, and its manufacturing and post-marketing surveillance capacity.

[4] The Diagnostics Consortium for COVID-19 is composed of: Bill & Melinda Gates Foundation, Clinton Health Access Initiative, Civil Society representation, FIND, Global Fund, Global Drug Facility/Stop TB Partnership, Médecins Sans Frontières, PAHO, UNDOS, UNDP, UNICEF, Unitaid, UNHCR, World Bank, and WHO.

[5] For example, original International Medical Device Regulators Forum members: Australia, Brazil, Canada, China, European Union, Japan and the United States.

Cost of the test

Ag-RDTs should generally be less expensive than NAATs, but costs will vary according to the specific test and the volume to be purchased, as well as whether or not additional supplies/equipment are required to perform the test, e.g., readers, controls. Testing using Ag-RDTs will also likely require a decentralized, trained workforce, which will increase the overall cost of testing.

Operational considerations

It is important that Ag-RDTs have the capacity to withstand temperature stress and have an extended shelf-life. Target shelf-life should be at least 12–18 months at 30°C and ideally 40°C. Staggered deliveries will be critical to offset challenges related to short shelf-lives. Careful planning is needed to avoid exposure of RDTs to high temperatures, with concerted preparation for handling at receipt, storage and distribution. All Ag-RDTs currently on the WHO EUL have maximum storage temperatures of 30°C, so cool storage may be required in some locations.

Considering the test procedure itself, the ideal workflow for Ag-RDTs would involve no sample preparation steps and no additional processing steps between placing the swab/sample in the buffer, squeezing and/or breaking off the swab, and applying the sample to the cartridge/strip. Other key operational considerations are whether the tests require the use of an instrument to interpret results, whether the tests can be run in batches and whether the tests have strict restrictions on the timing from collecting the sample to performing the test procedure. All Ag-RDTs currently on the WHO EUL are visual-read tests, which do not require any instrumentation; however, instrument-dependent Ag-RDTs are in the WHO EUL pipeline. Instrument-dependent Ag-RDTs may offer advantages (e.g., better performance, automated read-out and remote connectivity) and disadvantages (e.g., need for electrical supply, increased training needs, increased cost). These factors will need to be carefully considered during the product selection phase.

To encourage appropriate testing procedures, the manufacturers' instructions for use (IFU) should comply with *good practice* and should be available in the local language. Quick reference guides are available from some manufacturers and offer a nice complement to the IFU.

Specimen collection requirements

SARS-CoV-2 Ag-RDTs can have differing requirements for specimen types, number of processing steps, timings, instrumentation and interpretation of results. These factors will influence the amount of training and supervision required for implementation. An ease-of-use assessment should be considered to inform final product selection. Ag-RDTs are currently validated for limited specimen types, although studies are ongoing to expand validation. Countries should consider the range of validated specimen types when choosing tests.

The relative importance of these factors may vary depending on the country and setting, and countries should consider them in the context of the local setting in order to generate a shortlist of candidates. Countries may need to prioritize different product features based on different deployment settings. The final selection may be partly determined by budget envelopes, availability and supply chain considerations, which are discussed in the next section.

RDT supply chain management and logistics

The supply chain management and logistics of mobilizing Ag-RDTs involve several key components. Countries should consider the following key elements when developing supply chain and logistical plans.

Quantify and forecast demand for Ag-RDTs and PPE

Once an Ag-RDT has been selected or a shortlist has been developed, a three-step exercise is recommended to quantify and forecast country-specific demand for Ag-RDTs and PPE. This exercise consists of:

1. identifying appropriate epidemiological projections:
    - Using an existing model from the country's epidemiological division, or a modelling tool from *Imperial College London* or the WHO *COVID-19 Essential Supplies Forecasting Tool;*
2. building on the testing strategy to assign different use cases to NAATs or Ag-RDTs, or a combination of both; and
3. quantifying demand for testing (Ag-RDT and NAAT) and PPE *(11)* using a tool such as *the COVID-19 Essential Supplies Forecasting Tool:*
    - If using the Essential Supplies Forecasting Tool, total testing outputs should be differentiated by prioritized use case and by Ag-RDT or NAAT to determine the specific Ag-RDT need.

Secure funding for Ag-RDT testing services

Once the demand for Ag-RDTs has been quantified, the next priority step should be to mobilize sufficient diagnostic resources to cover the quantified Ag-RDT demand.

Countries should consider all budget requirements for obtaining quality-assured Ag-RDTs, including operating expenses (e.g., transport from manufacturer to port of entry, distribution, supply management, information and communication, training, supervision, QA, quality control [QC], monitoring and reporting) and not merely the cost of procuring and processing the RDTs.

Both existing and new funding streams should be leveraged. Identified resources could be specific to COVID-19 diagnostics, or part of general COVID-19 or health emergencies funding. New funding lines may also be considered or developed. Comprehensive resource mapping should be updated regularly to proactively identify and address funding gaps.

Initiate procurement processes

Once funding has been secured, the next step is to identify the preferred procurement channel(s) for Ag-RDTs. During the COVID-19 pandemic, countries may choose to procure Ag-RDTs through existing procurement channels, where the tendering process has already taken place. Some relevant procurement channels include:

- *WHO Supply Portal:* Please contact WHO country representatives for guidance on leveraging this procurement channel.
- *UNICEF Supply Division Supply Portal*: Please contact UNICEF representatives to initiate procurement.
- Wambo.org (Global Fund ordering platform): *Wambo.org* can be used for procurement using Global Fund resources for Global Fund-supported governments, using domestic resources, or using other sources of secured funding.
- The *African Medical Supplies Platform* portal for African Union Member States.
- Direct engagement with supplier representatives.

Prepare for and facilitate customs clearance

A streamlined customs clearance pathway should be established and communicated to relevant authorities in order to ensure that commodities are cleared immediately upon arrival in the country. In particular, it is important to coordinate with ministry of health-designated local authorities in order to identify how tax waivers can be obtained to expedite clearance processes and to map out timelines for obtaining duty waivers to inform COVID-19 testing implementation timelines.

Develop in-country distribution plans

In-country distribution plans should be prepared in advance to enable commodities to become immediately available at designated laboratories and health facilities. Plans should outline responsibilities for the ministry of health, national medical stores, implementing partners, reference laboratories and individual testing facilities. Once commodities are cleared by customs, the quality of the received goods should be verified prior to distribution. In the case of SARS-CoV-2 Ag-RDTs, this should include inspection of the integrity of the packaging and labelling. If available, an assessment of quality against well-characterized QC samples at reference laboratories is desirable. The tests should then be stored/transported according to the manufacturers' guidelines. A distribution plan should be developed to allocate and deliver assigned commodity volumes to laboratories, health facilities and other testing sites.

Monitor stock, track consumption and update procurement forecasts

As the demand for testing and availability of diagnostic and PPE supplies will continuously change as the pandemic evolves, procurement and supply management plans must remain flexible. Laboratories and health facilities should establish a process to periodically track and report commodity consumption (including that of Ag-RDTs) and develop a rapid ordering mechanism based on consumption reports. Supply management plans must include plans to maintain adequate supplies of the PPE required for Ag-RDT testing.

Training

Training and supervision are critical components of Ag-RDT QA. Ag-RDTs may be considered 'easy to use'; however, that does not negate the need for training and supervision, particularly as these tests are pushed out to remote settings and harsh conditions. Training processes for Ag-RDTs should include guidance on donning and doffing PPE, collecting samples, performing the test, interpreting the results and taking appropriate actions, biosafety and waste disposal, reporting/use of data, troubleshooting, QA and supply/stock management. A mixture of training media is preferred, including didactic and practical/wet-lab sessions as well as videos. Materials will need to be adapted to suit onsite versus remote learning settings. The quality of the trainers will be critical to successful training. Trainers should be carefully selected, as they will be the bedrock of a good training programme. Choose people with the following characteristics to be trainers:

1. Experience in training, especially in adult learning principles and conducting interactive presentations; training experience related to other RDTs is relevant.
2. Competency in the subject matter, particularly regarding QA and QC issues.
3. Excellent communication and presentation skills: able to use voice and body language well, set the tone of the training, convey the training content, show enthusiasm, encourage participation and provide positive reinforcement.
4. Available time to prepare and conduct the training.
5. Ability to manage the training: able to manage time, participants, locations and unexpected situations.

A training curriculum for SARS-CoV-2 Ag-RDTs has been developed by FIND and WHO, composed of 11 easily adaptable modules that cover topics spanning from sample collection to results reporting, with a special emphasis on biosafety. Examples of adaptable elements include the criteria for testing and management of test positive and negative cases. Modules are hosted on the *WHO Health Security Learning Platform* and are accompanied by useful tools such as checklists for setting up training workshops, site-readiness and supervisory checklists, competency assessments, sample log books and results reporting sheets. For successful completion, participants are required to complete theoretical and practical assessments. The training can be completed in a half to a full day, depending on the number of facilitators available and the number of modules that need to be covered based on the trainees' prior experience.

Given the limited implementation experience for SARS-CoV-2 Ag-RDTs, the first version of the training workshop materials will be updated as user feedback and more evidence become available.

QA processes

The pillars of QA for SARS-CoV-2 Ag-RDT testing services include procurement of a high-quality and suitable product, good transport and storage, verification of quality prior to deployment (if appropriate QC samples are available), training and supervision of end-users, and a system to communicate and address concerns. However, it is recognized that implementing all elements of QA may not be possible during the initial introduction of Ag-RDTs. QA for SARS-CoV-2 Ag-RDTs needs to be centrally coordinated and integrated with existing QA/supervision for rapid tests (e.g., for HIV, malaria) at peripheral health facilities wherever possible. Given resource constraints and the need for rapid deployment, the most efficient way to deploy SARS-CoV-2 Ag-RDTs is by using existing resources and systems. The following are key components of QA.

Lot testing

Given that SARS-CoV-2 Ag-RDTs are authorized for use under emergency conditions and have not undergone comprehensive and stringent regulatory review, verification of lot quality prior to the deployment of RDTs in the field is considered good practice, but only if well-characterized QC samples are available. Unfortunately, these materials are not yet widely available, nor are the procedures for their preparation. Therefore, the most feasible approach for new adopters may be to test using control materials either provided with the test kit or sold separately by the test manufacturer. In situations where control materials are unavailable, a small set of samples from SARS-CoV-2 NAAT-confirmed positive and negative samples may be tested in parallel to assess whether the new kit meets performance requirements.

Monitoring quality at the testing site

It is essential to conduct routine monitoring of Ag-RDT quality at the testing site after deployment. Such monitoring should incorporate use of QC, as well as routine monitoring of a minimum set of quality indicators. Where feasible, Ag-RDT results may be read by a second reader to reduce reading and transcription errors. A second reader may be beneficial for picking up tests with faint bands that may otherwise be missed, especially if large numbers of tests are being performed or testers are inexperienced.

QC

If positive and negative control materials are available, implementers should decide on a QC schedule that matches the availability of the controls, frequency of testing and the skills of the operators. If controls are included in the test kits, someone trained in the use of these materials should assess Ag-RDT performance every time a new box is opened. If testing rates are low and the same test box is used over a period of several weeks, then weekly QC could be considered if a separate supply of controls is available. If controls are not included in the test kits or operators have not been trained on QC procedures, then QC responsibilities may be best assigned to supervisors who can monitor stock quality during routine visits or at vulnerable locations along the supply chain. QC results should be analysed prior to the reporting of patient results. When unexpected results occur, a root cause analysis must be conducted, and corrective and preventive actions implemented. Therefore, there must be a system in place for communicating QC failures and for conducting investigations; otherwise, testing may be suspended for a prolonged period. In the case of QC failure, results of patient samples tested since the previous correct control results should be analysed and retested.

Monitoring quality indicators

All sites should rely on close routine monitoring of test results, e.g., to identify an unexpected frequency of negative, positive or invalid results at a particular site. A minimum set of key performance indicators or quality indicators should be routinely monitored at all testing sites. Standardized logbooks or registers should be available to enable tracking of tests performed, QC results, positivity rate, invalid rate, and the agreement between Ag-RDT and rRT-PCR results where confirmatory testing is performed. Countries are strongly recommended to leverage existing programmes and use data connectivity solutions to track quality indicators where feasible.

Supervision

Supervision is a critical part of QA for new sites and at the start of a new programme. Where possible, programmes should use existing systems and national standard supervisory checklists and guidelines for RDT supervision and QA. Regular contact with colleagues at the national reference laboratory and/or national coordinating team can help solve additional problems encountered in the field. Following Ag-RDT training and deployment, immediate and sustained follow-up is important to facilitate and support health workers to integrate Ag-RDTs into routine patient management and record-keeping. Support from regional health offices and other partners who are specialized in monitoring and evaluation (M&E) is instrumental in ensuring that the right tools and schedules are set for regular supportive supervision and overall post-implementation programme review.

Proficiency testing

Proficiency testing (PT) consists of sending a set of blinded samples (i.e., results not known to the site) to testing sites on a scheduled basis, usually one to three times per year, and comparing the results obtained by the testing site to the known results and to the results obtained by other participating sites. Discrepancies between the expected and actual results are then analysed and root cause analysis performed to guide corrective actions. PT is a recognized component of a comprehensive QA programme. When PT programmes are not yet established for SARS-CoV-2 Ag-RDTs, resources should focus on other core elements in the QA system, such as training, supervision, internal QC, proper transport and storage.

Data management and connectivity

Real-time data collection and transmission is critical for realizing the full value of Ag-RDTs so that decision-makers have up-to-date information to inform effective responses. This is particularly relevant for the COVID-19 response so as to quickly identify areas with outbreaks, track local epidemiology, and efficiently target resources and testing supplies.

Testing using Ag-RDTs presents unique data management challenges, as it supports decentralized testing and enables testing outside of traditional laboratory settings, typically in settings with no access to laboratory information management systems (LIMS/LIS) or health information systems (HIS). When implementing Ag-RDTs, data management should be considered in terms of what data points need to be recorded, how that data will be captured and how data systems need to be integrated to provide visibility. As the first step, countries need to define the data points required for any performance monitoring and reporting as part of their M&E priorities

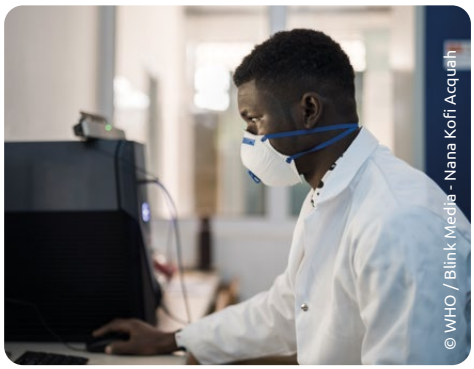
Data collection

Data collection at testing sites typically includes both diagnostic and test result information, and commodity supply and consumption. Commodity tracking should include periodic (e.g., weekly) reporting of current supply levels for all required commodities as well as consumption rates to inform when stocks need to be replenished. Where possible, commodity tracking data systems should be integrated with existing national supply management and logistics management information systems to enable visibility and alignment with established supply chain processes. Data collection of Ag-RDT results should be performed alongside testing as soon as results are available in order to reduce data-entry errors and enable real-time reporting of results.

There are several open-source tools available to countries for collecting COVID-19 data electronically in line with their M&E priorities. The digital health atlas from WHO *(https://digitalhealthatlas.org/en/covid-19/)* lists a number of such software tools available for countries to use in their COVID-19 response.

Data analysis and use

The impact of data collection is only realized with effective analysis and use of key data points. Implementers should map out how data need to flow between systems – from where data are entered to which reporting tools require access to data. Consideration also needs to be given to what data are required at different levels of decision-making in order to ensure that the data being collected are used in a timely manner to inform public health decisions.



To enable the different systems to interact seamlessly, it is important to ensure interoperability of the information technology (IT) systems in use and adherence to data exchange standards. Integrating data from different systems can require substantial development time. This should be planned for ahead of time by identifying development resources and pooling technical knowledge to facilitate integration efforts.

Connectivity for Ag-RDTs

The connectivity needs for Ag-RDTs depend on the format of the test and whether a reader device is used to interpret the result. For visual-read RDTs, the result is interpreted by the health care worker administering the test, and therefore data collection is done manually. In this situation, processes and systems should be put in place, if possible, to enable results to be entered in near real-time in a digital system. Solutions could range from the use of simple

electronic data entry forms to software designed for case management at the community health care level with functionalities to capture RDT-specific data.

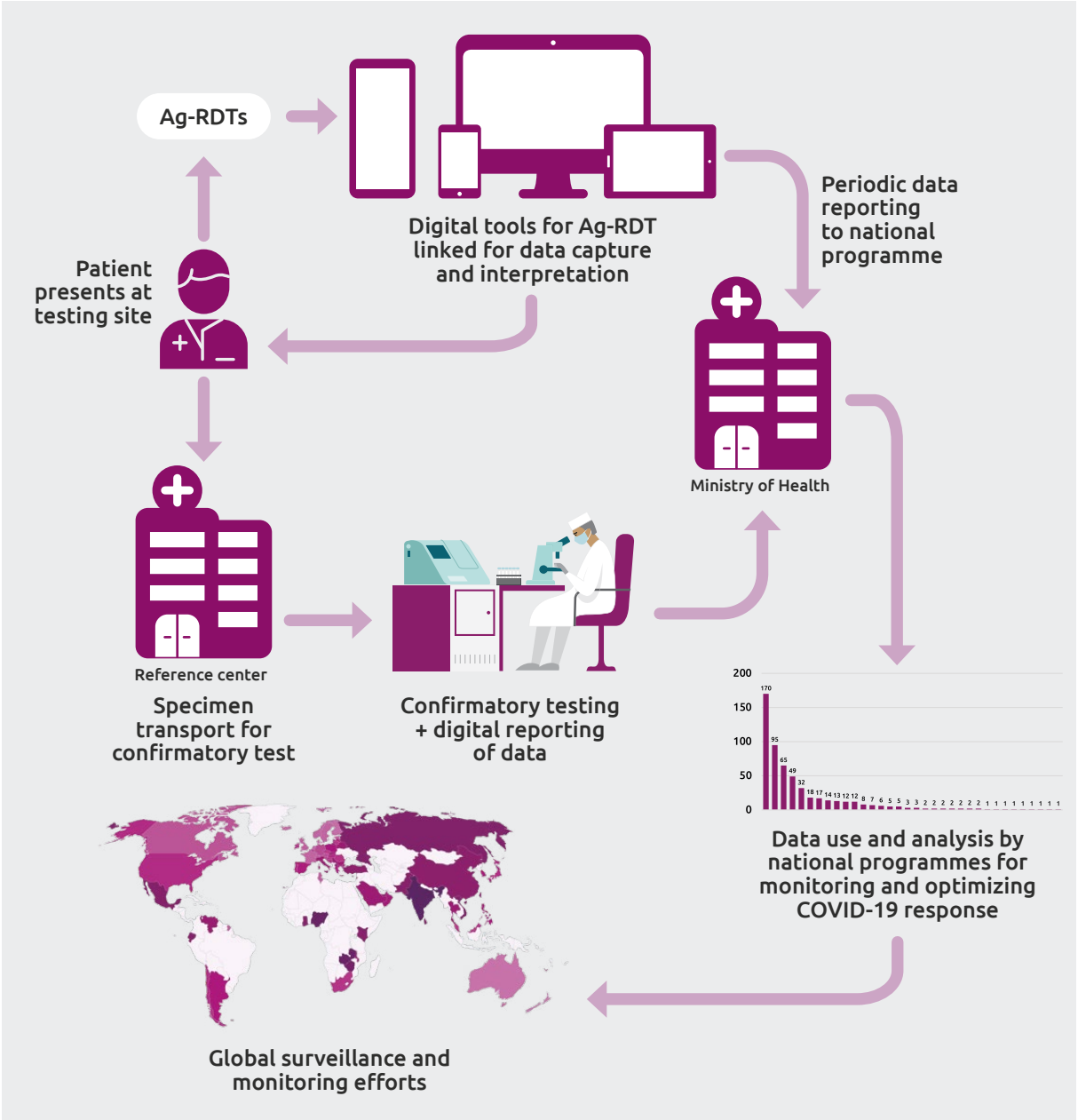
For device-based RDTs, instruments may come with connectivity functionality to automatically transmit test result information. If not, manual data entry is required similar to the visual-read tests. For device-based Ag-RDTs that do support connectivity, implementers should consider how these devices will be integrated with the relevant data systems.

Selecting the right tools

When selecting connectivity or data management tools, the following (non-exhaustive) considerations should be kept in mind: existing tools and interoperability between the tools; costs and resources required for implementation; and who has access and ownership of data collected via the technology platform. Care should be taken to ensure that implementers maintain appropriate ownership of their data according to local data laws and regulations.

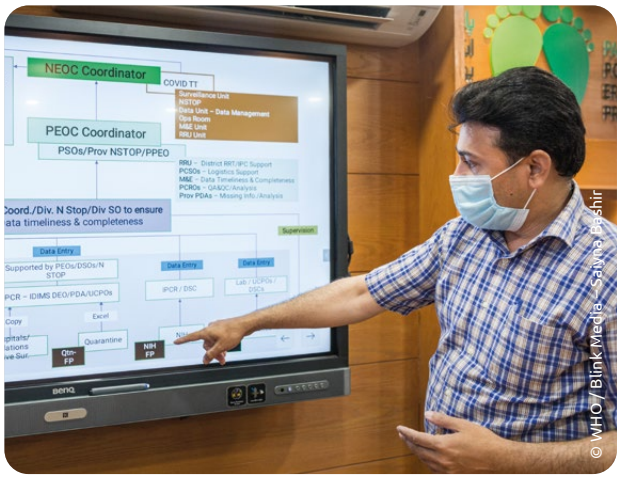
Fig. 4 illustrates how digital tools can be used to support Ag-RDT testing.

Fig. 4. Use of digital tools to support Ag-RDT testing



M&E

Routine M&E is an integral part of the COVID-19 response as a tool for programme management, tracking supply chain management, assessing test performance and measuring the impact of Ag-RDT introduction. For M&E of SARS-CoV-2 Ag-RDTs, countries should establish a standard indicator framework that can be applied across all testing sites, and set parameters for threshold values and trends that will trigger outbreak control actions or further investigation. Examples are provided in Tables 3–6. These frameworks and parameters should be based on current knowledge and regularly reassessed as local experience in SARS-CoV-2 Ag-RDT implementation evolves.



Routine M&E is recommended for all settings. Where possible, additional advanced indicators may be captured to enable intensified tracking of Ag-RDT performance and impact. However, this may require additional human resources or data systems to facilitate data collection and reporting.

Where possible, indicators should ideally be disaggregated by facility, facility level, facility type (public/private), administrative block/unit, district and region. Disaggregation to the extent possible is highly recommended to enable in-depth understanding of the situation and facilitate root cause analysis of any unexpected trends. The following indicators are suggested:

Programme M&E

These process indicators seek to track implementation of key activities related to Ag-RDT roll-out. These indicators should be reported at least monthly, with more frequent reporting (e.g., weekly) recommended during the initial stages of implementation.

Table 3. Programme M&E indicators

INDICATOR	DISAGGREGATION
# trainings conducted	By region, district, facility, facility level, facility type (public, private etc.).
# participants trained	By region, district, facility, facility level, facility type, health worker cadre (advanced).
# health facilities with one or more trained Ag-RDT testers	By region, district, facility, facility level, facility type (public, private etc.), health worker cadre (advanced).
# Ag-RDTs distributed to health facilities	By region, district, facility. Where multiple Ag-RDTs are in use, disaggregate by test type.
# Ag-RDTs received at health facilities	By region, district, facility. Where multiple Ag-RDTs are in use, disaggregate by test type.
# health facilities performing Ag-RDT testing	By region, district, facility, facility level, facility type (public, private etc.). Where multiple Ag-RDTs are in use, disaggregate by test type.
Of those health facilities performing Ag-RDT testing, how many perform Ag-RDTs only	
Of those health facilities performing Ag-RDT testing, how many perform Ag-RDTs and NAAT	
# health facilities performing Ag-RDT with stockout in the past month	By region, district, facility, facility level, facility type (public, private etc.). Where multiple Ag-RDTs are in use, disaggregate by test type.

Test uptake and performance: These indicators focus on understanding field test performance (where confirmatory testing is available) in different settings. They consist of a minimum set of indicators recommended for all health facilities and additional indicators that may be collected at a sample of health facilities where resources and data systems are available. During the early stages of implementation, it is recommended to track these indicators on a weekly basis in order to enable early identification of errors and prompt corrective action. Less frequent reporting (e.g., monthly) may be considered once routine testing has been ongoing for some time and the capacity to track performance and manage issues has been developed at the facility level.

Table 4. Test uptake and performance indicators

INDICATOR	DISAGGREGATION
# Ag-RDTs performed	Disaggregation by test type (where multiple Ag-RDTs are in use in a country). Disaggregation by batch number (advanced). Disaggregation by specimen type (advanced). Disaggregation by date of symptom onset (advanced). Disaggregation by patient category (advanced).
# Ag-RDT positive results	
# Ag-RDT negative results	
# Ag-RDT invalid results	
# samples tested by Ag-RDTs referred for NAAT	
# samples tested by Ag-RDTs that are retested using RDT	
# Ag-RDTs with faint bands (advanced)	
# Ag-RDTs with discrepancy between first and second reader (advanced)	
Time between specimen collection and test result reported to ordering health provider or patient (days, hours)	

Table 5. Correlation of Ag-RDT and NAAT results (advanced)

	AG-RDT POSITIVE	AG-RDT NEGATIVE	AG-RDT INVALID
NAAT POSITIVE			
NAAT NEGATIVE			
NAAT INVALID			

Table 6. Correlation of Ag-RDT 1 and Ag-RDT 2 results (advanced)

	AG-RDT 1 POSITIVE	AG-RDT 1 NEGATIVE	AG-RDT 1 INVALID
AG-RDT 2 POSITIVE			
AG-RDT 2 NEGATIVE			
AG-RDT 2 INVALID			

Monitoring: Frequent review of indicators and supervision of Ag-RDT testing sites should be planned soon after initial Ag-RDT deployment. Changes in testing strategy and the stage of the pandemic, as well as eligibility criteria for use of Ag-RDTs may affect both the rate of patients tested using Ag-RDTs and the test positivity rate. Such variations need to be taken into account when assessing the significance of changes in Ag-RDT results.

Evaluation: This is important for sustained follow-up and review of past activities. Internal and external evaluations should be planned for, after a given period of time following Ag-RDT deployment.

Current evidence on the widescale use of Ag-RDTs for COVID-19 is limited, so guidance will be updated as new information becomes available and countries gain experience of their implementation.

Communication and community engagement

Risk communication and community engagement are critical to ensure that Ag-RDTs are available to and used by the populations who need them. A communication plan should be included in the Ag-RDT implementation strategy and should address any expected gaps in knowledge and barriers to uptake in different settings and populations. Implementers working on communication and community engagement should consider the following components when planning their approach.

Advocacy is a critical component of communication and community engagement. Advocacy activities should include policy-makers, decision-makers and opinion leaders to mobilize uptake of Ag-RDT testing, build confidence in test results, and address any stigma and discrimination associated with COVID-19. The media are best positioned to rapidly raise awareness about Ag-RDTs and increase uptake, so early plans should be made to engage with print and broadcast media ahead of Ag-RDT roll-out. At the local level, community mapping should be used to identify "hot spot" areas with a high prevalence of COVID-19, vulnerable groups that may be missed, and key influencers who can support mobilization and community dialogue on Ag-RDT testing.

As a relatively new disease, community engagement should aim to provide basic facts and stimulate community dialogue about COVID-19, health care-seeking behaviours, testing procedures, stigma and discrimination, especially for those exposed to and recovered from COVID-19. Community engagement on testing and treatment for COVID-19 should address stigma and discrimination and attempt to influence social responses to those affected, at risk and infected. Communication and engagement responses need to recognize the diversity of communities and include representatives from the diverse groups involved in these efforts, such as community leaders and youth and women's groups. The approach should be inclusive and consider how to reach migrants, refugees, people with disabilities and other harder to reach populations. The data collected from these efforts should be used to advise advocacy and decision-making mechanisms.

Country example: communication and community engagement for SARS-CoV-2 testing in India

Nearly 30% of India's population live in urban slums, and COVID-19 cases are concentrated in 13 urban slums. People in the urban slums have fears about how they will be treated in isolation centres and concerns that health care workers may be responsible for spreading the virus. Prior to rolling out interventions to address these concerns, UNICEF, WHO and other partners undertook extensive mapping and assessment to identify who the community trusted most in terms of information about COVID-19. The research identified community doctors as the most credible source, and consequently community doctors and local NGO volunteers have been trained to positively influence community understanding and behaviour related to COVID-19.

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ANNEX: COUNTRY READINESS CHECKLIST FOR SARS-CoV-2 AG-RDT IMPLEMENTATION

To download the file: *https://apps.who.int/iris/bitstream/handle/10665/337937/WHO-2019-nCoV-Antigen_Detection_Readiness-2020.1-eng.xlsx*

Annex 1. Instructions to use the tool

	A	B
1		
2		**Purpose of the checklist**
3		The purpose of this checklist is to identify the topics that should be considered and addressed prior to the incorporation of antigen-detecting rapid diagnostic tests (Ag-RDTs) into a national COVID-19 diagnostic strategy. Further details on these topics can be found in a range of WHO guidance documents available on the WHO website.
4		
5		**Target audience**
6		The target audience consists of those policy-makers, regulatory authorities and officials responsible for the implementation of Ag-RDT use as part of the national COVID-19 diagnostic strategy.
7		
8		**Prioritization of activities to prepare for widespread Ag-RDT testing**
9		Activities can be carried out concurrently according to national priorities and capabilities. An order for conducting activities is suggested in the checklist. Activities shaded ▭ are planning activities that should be carried out at the beginning of the implementation process. Activities shaded ▭ are more operational and can be implemented either at the beginning of the process or when progress has been made on the planning side. All activities should be completed by the time testing with Ag-RDTs begins.
10		
11		**Responding to the questions**
12		Select the appropriate response from the dropdown list adjacent to each question. The options are: • Completed • In progress • Not started • Not applicable The responses are automatically carried over to the Results tab.
13		
14		**Results**
15		A summary of the responses recorded is displayed under the Results tab, both as a table and as a pie chart. The responses to all questions are displayed and then the responses to the planning and operational questions are displayed separately. These summaries are a count of the number of activities for which a particular response was recorded. There is no weighting of activities in terms of complexity or the likely time it would take to complete them.

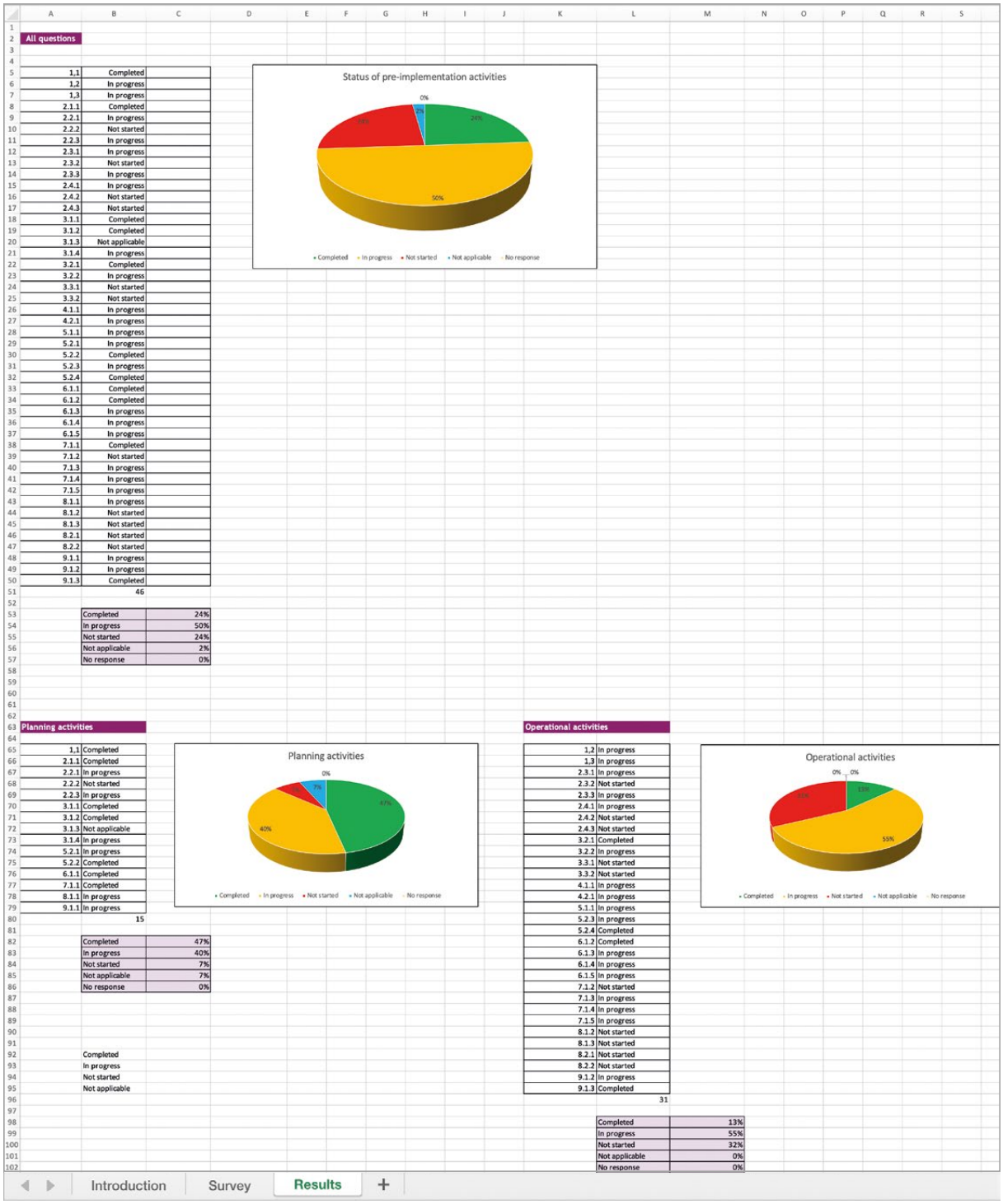
Introduction | Survey | Results | +

Annex 2. Example of inputs to the checklist

	A	B	C
1			
2		Country	
3			
4		Names and organizations of those completing the checklist responses	
5			
6			
7			
8		**Part A: Integrating SARS-CoV-2 antigen-detecting rapid diagnostic testing into a national response plan**	
9	**1**	**Programme planning**	
10	1,1	**Has a national diagnostic committee been established to:** • review and update policies and guidelines • prepare and oversee implementation plans • coordinate partner activities • review progress and monitor activities • prepare a budget and manage resource mobilization?	**Completed**
11	1,2	**Has a comprehensive review of COVID-19 testing in the country been conducted? Such a review could include a description of:** • current policies, regulations and practices, including case definitions and testing algorithms • where testing is done (which types of laboratories) • laboratory resources available, including reference laboratories • human resources • who should be tested, where and when • cost, how much and who pays, and • cultural barriers to testing.	**In progress**
12	1,3	**Have the roles and responsibilities of those implementing Ag-RDT testing at central, subnational and peripheral levels of the health system been identified?** **Areas of responsibility include:** • planning • policy development and dissemination • procurement (reagents, controls, personal protective equipment [PPE] and other equipment) • transport of reagents and supplies • storage and stock management • quality management • training.	**In progress**
13			
14	**2**	**Policies and technical guides**	
15	2,1	Relevant national policies to include SARS-CoV-2 Ag-RDTs	
16	2.1.1	**Have relevant national policies been reviewed and updated if necessary?** **These include:** • national laboratory policies • national biosafety policies and guidelines • national laboratory quality standards • guidelines on waste management • procurement policies.	**Completed**
17	2,2	Regulatory issues	
18	2.2.1	**Have regulatory issues around Ag-RDTs been addressed?** Ag-RDTs are diagnostic devices and must therefore comply with safety procedures (i.e., samples must be treated as potential biohazards). Their use results in the generation of contaminated waste that must be disposed of and destroyed in the same way as other laboratory infectious waste.	**In progress**
19	2.2.2	**Have regulations around health workers been reviewed?** Are health workers at all sites where Ag-RDT use is planned authorized to use them?	**Not started**
20	2.2.3	**Have safety and waste management regulations been reviewed?** The introduction of large-scale Ag-RDT use at sites with limited facilities for waste disposal may create problems. Do national guidelines for disposal of contaminated waste adequately address this situation?	**In progress**
21	2,3	Prepare national guidelines	

Introduction | Survey | Results | +

Annex 3. Example of results obtained when using the tool



All questions

1.1	Completed
1.2	In progress
1.3	In progress
2.1.1	Completed
2.2.1	In progress
2.2.2	Not started
2.2.3	In progress
2.3.1	In progress
2.3.2	Not started
2.3.3	In progress
2.4.1	In progress
2.4.2	Not started
2.4.3	Not started
3.1.1	Completed
3.1.2	Completed
3.1.3	Not applicable
3.1.4	In progress
3.2.1	Completed
3.2.2	In progress
3.3.1	Not started
3.3.2	Not started
4.1.1	In progress
4.2.1	In progress
5.1.1	In progress
5.2.1	In progress
5.2.2	Completed
5.2.3	In progress
5.2.4	Completed
6.1.1	Completed
6.1.2	Completed
6.1.3	In progress
6.1.4	In progress
6.1.5	In progress
7.1.1	Completed
7.1.2	Not started
7.1.3	In progress
7.1.4	In progress
7.1.5	In progress
8.1.1	In progress
8.1.2	Not started
8.1.3	Not started
8.2.1	Not started
8.2.2	Not started
9.1.1	In progress
9.1.2	In progress
9.1.3	Completed
	46

Completed	24%
In progress	50%
Not started	24%
Not applicable	2%
No response	0%

Status of pre-implementation activities

Planning activities

1.1	Completed
2.1.1	Completed
2.2.1	In progress
2.2.2	Not started
2.2.3	In progress
3.1.1	Completed
3.1.2	Completed
3.1.3	Not applicable
3.1.4	In progress
5.2.1	In progress
5.2.2	Completed
6.1.1	Completed
7.1.1	Completed
8.1.1	In progress
9.1.1	In progress
	15

Completed	47%
In progress	40%
Not started	7%
Not applicable	7%
No response	0%

Completed
In progress
Not started
Not applicable

Operational activities

1.2	In progress
1.3	In progress
2.3.1	In progress
2.3.2	Not started
2.3.3	In progress
2.4.1	In progress
2.4.2	Not started
2.4.3	Not started
3.2.1	Completed
3.2.2	In progress
3.3.1	Not started
3.3.2	Not started
4.1.1	In progress
4.2.1	In progress
5.1.1	In progress
5.2.3	In progress
5.2.4	Completed
6.1.2	Completed
6.1.3	In progress
6.1.4	In progress
6.1.5	In progress
7.1.2	Not started
7.1.3	In progress
7.1.4	In progress
7.1.5	In progress
8.1.2	Not started
8.1.3	Not started
8.2.1	Not started
8.2.2	Not started
9.1.2	In progress
9.1.3	Completed
	31

Completed	13%
In progress	55%
Not started	32%
Not applicable	0%
No response	0%

Operational activities

Introduction | Survey | Results | +

NOTES

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