Use of SARS-CoV-2 antigen-detection rapid diagnostic tests for COVID-19 self-testing

Interim guidance
9 March 2022

World Health Organization

Key points

- COVID-19 self-testing, using SARS-CoV-2 Ag-RDTs, should be offered in addition to professionally administered testing services (S*trong recommendation, low to moderate certainty evidence*). This recommendation is based on evidence that shows users can reliably and accurately self-test, and that COVID-19 self-testing is acceptable and feasible and may reduce existing inequalities in testing access.
- The role and use of COVID-19 self-testing–including why, where and how it should be used–will need to be adapted to national priorities, epidemiology, resource availability, and local context with community input. Clear and up-to-date messaging will be needed to ensure self-test users can understand when to test, the meaning of their test results and post-test responsibilities.
- Self-testing should always be voluntary and never mandatory or coercive. It is important that in certain settings, such as schools and workplaces, self-testing costs are not borne by students or workers.
- Access to affordable and quality-assured SARS-CoV-2 Ag-RDTs, including for self-testing, should particularly be prioritized for settings where there is limited access to NAAT. COVID-19 self-test kits should meet the existing World Health Organization (WHO) standards for Ag-RDTs (≥ 80% sensitivity and ≥ 97% specificity among symptomatic individuals).
- COVID-19 self-testing can be considered for both diagnostic and screening purposes. Depending on the epidemiological situation, a positive self-test result in symptomatic individuals or those with recent exposure could be used for diagnosis, and to facilitate linkage to clinical care and therapeutics.
- For screening purposes, a negative self-test result could enable participation in an activity, such as group activities or indoor gatherings, and confirmatory testing for positive results can be considered.
- Each country is facing a different situation in the pandemic depending on several factors including the intensity of SARS-CoV-2 circulation, amount of population level immunity, capacities to respond and agility to adjust measures. Timely and accurate diagnostic testing for SARS-CoV-2, the virus that causes COVID-19, is an essential part of a comprehensive COVID-19 response strategy. As the pandemic continues and the virus evolves, policy adjustments related to SARS-CoV-2 testing approaches and services, including COVID-19 self-testing, will be needed.

Introduction

Timely and accurate diagnostic testing for SARS-CoV-2, the virus that causes COVID-19, is an essential part of a comprehensive COVID-19 response strategy. Diagnostic testing for SARS-CoV-2 supports both individual-level case finding and community-level actions to inform the overall public health response. There are two types of tests currently used for the diagnosis of SARS-CoV-2: (1) detection of viral RNA through NAAT, such as real-time reverse-transcription polymerase chain reaction (rRT-PCR); and (2) detection of viral antigens through immunodiagnostic techniques such as lateral flow assays, commonly called Ag-RDTs *(1, 2)*. Though lab-based NAAT is considered the reference standard, WHO recommends Ag-RDTs as a decentralizable, faster and reliable option for SARS-CoV-2 diagnosis that is often less-expensive. Additionally, Ag-RDTs are effective for identifying people who are most infectious, whereas a limitation of rRT-PCR is that it can lead to persistent positive results well past the period of transmission and recovery *(3, 4)*. Several Ag-RDTs tests have been approved through the WHO Emergency Use Listing (EUL) procedure, to assist global procurement of quality-assured products.

In many settings, community access to COVID-19 testing is limited, and introduction of COVID-19 self-testing using Ag-RDTs–in which individuals collects their own specimen, perform a simple rapid test and interpret their test result themselves at a time and place of their choosing–has been proposed as a strategy to expand access to testing. Drawing on growing knowledge and experience implementing self-testing *(5-10)*, and existing WHO guidance supporting self-care and self-testing across other disease areas *(11-13)*, this interim guidance provides a new recommendation that COVID-19 self-testing, using SARS-CoV-2 Ag-RDTs should be offered as part of SARS-CoV-2 testing services.

This guidance will enable countries to make decisions on including COVID-19 self-testing as an additional part of overall SARS-CoV-2 testing services. It also includes implementation considerations that can guide decisions on whether and how to adopt self-testing in different contexts, including the populations being prioritized; the disease prevalence in that population; and the impact on accessibility of testing, health care services and result reporting. The goal is contributing to effective management of COVID-19 as a public health problem.

Intended audience

This guidance on the use of Ag-RDTs for COVID-19 self-testing will be relevant to policy makers, programme managers, implementers, health workers and pharmacists responsible for planning and implementing SARS-CoV-2 testing, prevention, care and treatment services, particularly in low- and middle-income countries. This updated guidance may also be informative for educational institutions, workplaces, border health services, organizers of group and mass gathering events and civil society and community-based organizations, including those working with or led by populations most affected by and/or who may be at increased risk of severe COVID-19.

Previous SARS-CoV-2 Ag-RDT testing guidance

In September 2020, WHO released its first interim guidance advising on the role of Ag-RDTs in the diagnosis of COVID-19 *(2)*. In October 2021, WHO released an update and issued interim guidance on the use of Ag- RDTs in the diagnosis of SARS-CoV-2 infection *(1)*, providing more detail on the populations or settings in which Ag-RDTs used by trained operators may have the most impact. This interim guidance on the use of Ag-RDTs for COVID-19 self-testing should be read in conjunction with the latest guidance on the use of Ag-RDTs and recommendations for national testing strategies and diagnostic testing capacity *(14)*.

Recommendation: COVID-19 self-testing

COVID-19 self-testing, using SARS-CoV-2 Ag-RDTs, should be offered in addition to professionally administered testing services

(Strong recommendation, low to moderate certainty evidence)

Remarks:

- **Human rights:** COVID-19 self-testing is a personal choice. It can expand access to testing by providing an additional way for people to test and make personal risk-based decisions that may affect their health and the health of their families and communities (e.g. to protect those most affected by or who may be at increased risk of severe COVID-19, or to enable individual participation in activities).

  COVID-19 self-testing, as with any testing, should always be voluntary and never mandatory or coercive. The practice of self-testing, regardless of test results, must always be free from stigma and discrimination.

  Self-testers will need to be provided with adequate information on when to test and nationally-relevant post-test responsibilities and actions. Anyone uncertain of their COVID-19 self-testing result, or desiring alternative professional testing services, should be encouraged to access other testing options where available and in line with the latest national guidance.

  Countries should consider reviewing and contextualizing their existing policies on the age of consent to include COVID-19 self-testing and the role of assisted and caregiver-led self-testing by a parent or guardian. For adolescents and mature minors, age-of-consent policies that enable access without parental consent are important to enable COVID-19 self-testing when needed.

- **Epidemiology:** The implications of a test result are not only a function of its inherent sensitivity and specificity. The result is also dependent on the prevalence of SARS-CoV-2 infection in the population prioritized for testing. When using COVID-19 self-testing in settings with higher pre-test probability i.e., higher likelihood of an individual having SARS-CoV-2 infection, such as in places where there is ongoing community transmission or when an individual is at high likelihood of exposure (e.g. contacts, health and care workers)–the positive predictive value of the test is high. This means a positive self-testing result is likely to be a true positive. When COVID-19 self-testing is used in a low pre-test probability setting (e.g. when testing someone without symptoms and no known exposure to the virus or when there is no or low community transmission), the positive predictive value of self-testing is lower, which will lead to increased false-positive results. In these situations, the negative predictive value of COVID-19 self-testing is high, meaning the risk of a false negative is lower.

Policymakers and implementers need to consider reasons for testing and evolving epidemiology when COVID-19 self-testing is offered along with other testing approaches. Clear and up-to-date messaging will need to be provided to health workers, individuals and communities so that self-testers can understand the meaning of their test results and what actions to take post-test. See WHO guidelines on COVID-19 transmission scenarios, public health and social measures, and public health surveillance for COVID-19, including up-to-date definitions of contacts and cases for further details *(15-18)*.

- **Evolving context, priorities and messaging:** Health worker and community awareness of and engagement in adapting COVID-19 self-testing is important for successful implementation. As local epidemiology changes, information on self-testing that is context-specific, correct, clear, concise and age-appropriate should be made available. Messaging should include when self-testing should be prioritized or deprioritized for specific populations or settings, the meaning of a positive or negative self-test result and any recommended follow-up actions after self-testing.

  Messages will vary based on current local situations but should be consistent with national policies. They may include information on result reporting *(17)*, quarantine *(19)*, contact tracing *(18, 20)*, when to seek confirmatory testing and retesting *(1)*, availability of treatment services *(21, 22)*, and latest information on infection prevention and control, masking and physical distancing *(23-26)* and public health and social measures *(15, 16)*.

- **Emerging SARS-CoV-2 variants:** This recommendation is valid for detection of all reported SARS-CoV-2 variants of concern *(27)*. As SARS-CoV-2 continues to evolve, policies will need to take into consideration circulating variants and test performance. The accuracy of COVID-19 self-testing needs to be continually assessed and reviewed with the emergence and spread of new variants, just as it is for professional-use NAAT and Ag-RDT.

Justification:

Evidence on the effectiveness of the COVID-19 self-test was derived from two systematic reviews that included two studies (three data sets) reporting on performance and accuracy and 11 studies (18 data sets) reporting on utility. Included studies were observational and from high-income settings where self-testing was generally conducted at home, and self-tests were presumably provided free of charge. Studies included the general population, as well as health workers, primary and secondary school aged children and parents, university students, school staff and teachers, and contacts of confirmed and probable SARS-CoV-2 cases. See Web Annex A for further details.

Additional evidence on self-testing, including from low- and middle-income countries, was compiled and reviewed and is available in Web Annexes B-E on the WHO Website. This evidence builds on a growing body of evidence supporting the use of self-testing and self-care for other disease areas *(11-13)*.

Considering all reviewed evidence, COVID-19 self-testing was found to achieve accuracy that is similar to professional testing with Ag-RDTs. Compared to existing or no testing options, COVID-19 self-testing has the potential to increase access, reduce time to receiving results and taking post-test actions, achieve good uptake, inform individual risk-based decision making and enable diagnosis of cases that may otherwise have been missed. No social harm was reported or identified, but potential for a false sense of security with negative test results was noted. Including messages on result interpretation and potential for re-testing can be used to help mitigate these challenges.

COVID-19 self-testing was consistently acceptable to stakeholders, feasible to implement in a range of settings and would reduce existing inequalities in testing access. Costs and resource needs for self-testing are uncertain and variable based on different contexts, epidemiology and whether societal factors and individual opportunity costs are included in decision-making. However, projections of the potential unit cost for self-tests were assessed as potentially comparable to or lower than professional-use SARS-CoV-2 Ag-RDTs *(28)*.

The Guideline Development Group (GDG) deemed the evidence to be of low to moderate certainty overall and determined that the benefits of COVID-19 self-testing outweigh the potential of harm. By full consensus, the GDG decided to strongly recommend COVID-19 self-testing as an additional testing approach. The strength of the recommendation and the quality of evidence were determined through the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach *(29)*. Box 1 provides a summary of key findings from the systematic reviews, values and preferences, feasibility and resource-use. Web Annex E also provides a detailed evidence-to-decision-making summary.

Box 1. Key findings from the reviewed evidence on COVID-19 self-testing using SARS-CoV-2 Ag-RDTs

- **COVID-19 self-testing is feasible, and self-testers can reliably and accurately perform SARS-CoV-2 Ag-RDTs, as compared to trained testers**
  - Self-testing achieves good performance (sensitivity and specificity) and a high-level of agreement and usability when compared with Ag-RDTs performed by trained testers.
  - Some user errors occur with self-testing, but errors documented did not impact self-test results. Users report confidence about self-testing and indicate it is easy.
  - Demonstrations (in-person and video) are useful for optimizing self-test performance, and some groups, e.g. older age groups, will likely benefit from additional support.

- **Offering COVID-19 self-testing is acceptable and has the potential to achieve good uptake**
  - Many people are willing and able to perform self-testing using SARS-CoV-2 Ag-RDTs across a wide range of populations and settings.

- **Offering COVID-19 self-testing has the potential to enable timely diagnosis and prompt risk-based decisions and post-test actions**
  - Self-testing provides individuals with their test results within 20-30 minutes, which can be faster than available provider-administered testing using Ag-RDTs and NAAT. Self-testing can enable individuals to make quicker post-test actions, including decisions that may affect their health and the health of their families and communities.
  - Negative self-test results may inform individual decisions about whether to continue or resume activities and to decide on when and how to access further confirmatory testing.

- **Offering COVID-19 self-testing has the potential to enable additional individual and social benefits**
  - Self-testing will increase equity by providing an additional testing option and has potential to reach individuals who otherwise may not have access to tests or are hesitant to take one.
  - Self-testing can provide an alternative to or reduce quarantine and can enable individuals to engage in activities that they otherwise might forgo, such as family visits to care homes.
  - Self-testing can be used as a tool to prevent absenteeism from school and among essential workers such as health workers, firefighters and police.
  - Self-testing can increase convenience and provide a sense of safety and well-being among some users and their families and communities.

- **COVID-19 self-testing costs and resource requirements are uncertain and variable**
  - Costs for implementing self-testing could be high in some settings, whereas costs in other settings could be moderate or result in cost savings based on epidemiology and whether societal benefits and individual opportunity costs are included in the assessment.
  - Access to free or low-cost self-testing may be available in some settings, but overall costs to individuals and the health system are uncertain and are likely to vary widely.

- N**o specific harms identified or reported following COVID-19 self-testing**
  - It is important to monitor for potential harm and address individual and community concerns, such as a potential risk of a false sense of security with negative test results**.** Messaging on result interpretation and potential for repeat testing will be important for mitigating such challenges.
  - Evidence is limited and no data identified on the impact of self-testing on mortality and morbidity or broader societal benefits.

Implementation and monitoring considerations:

Each country is in a different situation in the COVID-19 pandemic depending on several factors including the intensity of SARS-CoV-2 circulation, amount of population level immunity, community trust, capacities to respond, and agility to adjust measures. As the pandemic continues and the virus evolves, timely and accurate diagnostic testing for SARS-CoV-2 will remain an essential part of a comprehensive COVID-19 response strategy, but policy adjustments are expected. The specific role and use of COVID-19 self-testing–including where, how and to whom it should be offered–will need to be adapted to suit national priorities, epidemiology, resource availability and the local context and health system. Introduction of self-testing will need to be considered and planned in relationship to a country's overall strategy and goals in the context of the COVID-19 response. Plans will also need to prioritize and enable access to self-testing

for populations at greatest risk of severe COVID-19 disease and with greater challenges accessing existing testing services. National policies should be evidence-based, agile and adjusted as needed taking into consideration these and other factors.

The following WHO principles for implementing SARS-CoV-2 Ag-RDTs are applicable to self-testing policy and regulatory planning *(30)*:

- Access to affordable and quality-assured SARS-CoV-2 Ag-RDTs including self-testing, should be prioritized particularly for settings that have limited access to NAAT. **Clear national registration and regulatory requirements** are important for ensuring available Ag-RDTs for self-testing are quality-assured and meet minimum performance requirements. Member states should consider using COVID-19 self-tests approved through the WHO EUL procedure *(31)*. In the absence of EUL-approved products, some Members States may consider tests approved by regulators that are founding members of the Global Harmonization Task Force (GHTF) *(32)* and have been assessed as per published national technical requirements. Availability of COVID-19 self-testing products of poor or unknown quality can negatively affect programming and may undermine public confidence in testing services.
- **Test performance.** The guidance in this document is based on use of COVID-19 self-testing Ag-RDTs that have equivalent clinical performance to professional Ag-RDTs. WHO recommends Ag-RDTs meet minimum performance requirements of ≥80% sensitivity and ≥97% specificity when compared to NAAT among symptomatic individuals *(33)*. For additional details on the relationship between test performance, prevalence and predictive values of results using Ag-RDTs, please refer to the Annex of WHO's interim guidance on ***Antigen-detection in the diagnosis of SARS-CoV-2 infection*** *(1)*. Simple calculators may also be useful, such as the '*Interpreting a COVID-19 test result'* tool *(34)*.
- **Storage, operation and disposal information**. COVID-19 self-testing kits should be stored and operated according to the specified temperature ranges noted in the instructions for each kit. They should be disposed of according to the manufacturer's instructions provided. It should be possible to dispose of the test by depositing it in the general waste system. It is important that these details can be clearly understood by end-users.
- **Existing quality assurance procedures** should be adapted to include COVID-19 self-testing kits. As self-tests are implemented, this may include lot testing and other post-market surveillance activities. These procedures are important for verifying the quality of nationally registered COVID-19 self-testing products, identifying instances where products are not performing as expected and enabling corrective actions and quality improvement.
- **Resource requirements and systems** for the procurement, distribution, stock monitoring and consumption tracking of COVID-19 self-tests should be considered as part of the overall testing system.
- National programmes should **routinely review the role of COVID-19 self-testing** within their testing programmes and adjust implementation and messaging as needed.

Results interpretation when using self-testing for diagnosis or screening

COVID-19 self-testing can be considered for diagnostic purposes in settings with ongoing community transmission *(16, 17)* and when used by symptomatic individuals or those who have been recently exposed to SARS-CoV-2. COVID-19self-testing can also be considered for screening purposes irrespective of the level of community transmission.

COVID-19 self-testing is, however, a complementary testing approach and does not necessarily replace professional testing services using Ag-RDTs and NAAT. Anyone uncertain about a self-test result should always be encouraged and supported to access provider-delivered SARS-CoV-2 testing approaches according to national guidelines.

Diagnosis

When used for diagnosis, self-tests will be more likely to detect current infection when performed within the first 5-7 days of the disease course.

Where there is ongoing community transmission *(16, 17)*, and testing is targeted towards individuals with symptoms and/or recent exposures (such as contacts or health and care workers), COVID-19 self-testing can be considered for **diagnostic purposes**, without a requirement for further confirmatory testing. In these settings:

- An individual with a positive self-test result can be considered to be a probable (or confirmed) case of SARS-CoV-2 infection (depending on national policy) *(16, 17)*. Post-test actions should then be taken according to current national guidelines, such as self-isolation and notification of contacts. Infection prevention and control practices should also be practiced, such as masking and physical distancing. Further details on post-test actions are provided in WHO guidance on contact tracing and quarantine *(18-20)*, on public health and social measures *(16, 17)*, on infection, prevention and control *(23-25)*, and on clinical management including isolation *(22, 35)*.

- An individual with a positive self-test result who is symptomatic, should consider seeking clinical care services, according to national COVID-19 care pathways, which may include therapeutic options for COVID-19. Individuals with risk factors and/or severe symptoms (chest pain, shortness of breath, dizziness, etc) should not delay seeking clinical care *(21, 22)*. In some settings, confirmatory testing may be desired before prescribing therapeutics, but this should not delay timely administration. Professionally administered Ag-RDTs could be considered to prevent delays. Further details are provided by WHO guidance on therapeutics *(21)* and clinical management of COVID-19 *(22)*.
- An individual with a negative self-test result is less likely to be infected at the time of testing. However false-negative results can occur, especially among individuals who test early and may have lower viral loads. All self-testers should be made aware of the possibility of false-negative results.
- A negative self-test result in someone who has had a recent confirmed or probable exposure or is experiencing symptoms should be advised to continue standard infection prevention and control practices and to consider re-testing, e.g. 24 to 48 hours later. It is important that individuals who report symptoms, but who are self-test negative, be provided with information on the importance of testing for other illnesses and are advised on where and how to access other health care services. Re-testing can be performed through self-testing or professional testing.

Screening

Self-testing for screening purposes can be considered among individuals without symptoms or known exposure to SARS-CoV-2 irrespective of intensity of community transmission *(16, 17)*. For this application, a negative self-result could enable participation in an activity and, depending on the epidemiological situation, a positive self-test result may be followed by confirmatory testing.

In settings with no or low community transmission *(17)*, COVID-19 self-testing could be **used for screening** individuals with symptoms and/or with recent exposures (such as contacts, or health and care workers). In these settings:

- A negative self-test result is consistent with absence of current infection or lower viral loads. Information should be provided on the possibility of false-negative results and on infection prevention and control and public health and safety measures, including masking and physical distancing.
- An individual with a positive self-test result may consider seeking confirmatory testing (because the positive predictive value of a test is lower in low prevalence settings) and exercise infection prevention and control practices, masking and physical distancing, according to current national guidelines until the confirmatory test result is available. For more details on when to consider a confirmatory test, refer to existing guidance on the use of Ag-RDTs *(1)*.

The benefit of using COVID-19 self-testing to implement widespread asymptomatic testing in settings with low or no community transmission remains uncertain.

Box 2. Key points on results interpretation by setting

When to use self-testing for diagnostic purposes:
- ongoing community transmission
- testing in individuals with symptoms ≤ 7 days
- testing in individuals with recent exposures (such as close contacts and health and care workers) who are asymptomatic
- testing to detect and respond to suspected outbreaks.

How to interpret self-testing results for diagnosis:
- An individual with a positive self-test result can be considered a probable case of SARS-CoV-2 infection and should take post-test actions, including infection control measures, according to current national guidelines.
- A negative self-test result is consistent with absence of current evidence of infection, but individuals should be made aware of the possibility of false-negative results. Individuals self-testing negative–especially those with persistent or progressing symptoms–should consider re-testing, e.g. 24 to 48 hours later and/or should seek testing for other diagnoses, including for other respiratory infections. Re-testing can be performed through a self-testing or through professional testing.

When to use self-testing for screening purposes:
- testing in asymptomatic individuals with unknown or no known exposure who want increased confidence that they do not have a SARS-CoV-2 infection.

How to interpret self-testing results for screening:

- A negative self-test result is consistent with absence of infection, especially when there is low or no community transmission, but the possibility of false negative results should be noted.
- Positive self-test results may be followed by confirmatory testing, and individuals should exercise infection prevention and control practices according to current national guidelines while arranging it.

Messaging and support for using self-tests

As noted in the Recommendations section of this document, it is important to provide self-testers with age-appropriate, accurate and accessible information, including messages explaining the meaning of a positive or negative result in different settings and contexts. For example, a positive self-test result likely indicates active SARS-CoV-2 infection, but false-positive results may be more likely when self-testers have no known exposure and are in settings with low-to-no community transmission. In a similar vein, a negative test result indicates a lower likelihood of current SARS-CoV-2 infection, but false-negative results can occur and may be more likely in individuals who test very early after infection with SARS-CoV-2. Messages that include information about when and how to seek confirmatory testing after a positive result and considerations for confirmatory re-testing for those concerned about a false negative self-test result can be useful. Several countries have developed standard messages and information *(36)*, which may be useful for adaptation to suit national guidance and priorities. Community members, lay providers and peers can also play a role in developing and disseminating these messages about the proper use of COVID-19 self-testing, correct interpretation of self-testing results, appropriate post-test actions and informed risk-based decision-making.

Self-testers value high-quality test kits with clear and simple instructions. Distribution of kits must always be accompanied by appropriate instructions for use and can include supportive materials (for example, hotlines, brochures, peer-led messages, videos and web-based support in local languages). Support options that include an in-person demonstration or assistance or web-based or other video instructions may be considered during early implementation and for populations that can benefit from additional support, such as older age groups *(6)*. Training health workers, community members, caregivers and managers of congregate settings like prison wardens, church and schools to help support testing procedures, answer questions and train others on how to test and what to do dependent on results can also be helpful *(7, 8)*. Such support can help optimize self-testing implementation and overall accuracy by minimizing user errors *(6)*.

Fears and myths surrounding COVID-19 and COVID-19 self-testing must be counteracted early by local messaging. It is important to identify where there is support and where there is resistance to self-testing implementation so that correct messages and information can be delivered and supportive stakeholders engaged.

Service delivery

It is important to identify optimal approaches to deliver COVID-19 self-testing based on the latest epidemiology, identified gaps in testing and broader response, available resources and the needs of populations that have been prioritized as part of the COVID-19 response. Any service delivery approach or distribution channel (for example, health facilities, care homes, community settings, workplaces, educational settings, pharmacies, private sector shops or online, as well as secondary distribution via peers or family members) needs to be agile to reflect the evolving epidemiology and adapted to suit the local context and community preferences. When planning service delivery, it is important that populations most at risk of severe COVID-19 disease, and those with greater challenges accessing existing testing services receive prioritized access to self-testing.

COVID-19 self-testing is being implemented in many ways worldwide. Respondents to a recent WHO survey (Web Annex D) indicated that COVID-19 self-testing is available in over 100 countries and mostly distributed by pharmacies and in retail settings but is also reported to be accessible through the internet and digital applications, faith-based settings, community distribution and secondary distribution such as from someone confirmed to be infected to their contacts. In many settings, it was reported that self-testing is being used among both asymptomatic and symptomatic individuals, including those in educational settings, mass gatherings, non-health care settings and as part of personal decision-making.

Additional strategies for implementing COVID-19 self-testing identified across the literature included using self-testing to:

- test health workers in hospitals to reduce absenteeism and staff-to-staff and staff-to-patient transmission *(5)*;
- enable visitor entry and reduce risks to care home residents and staff *(7)*;
- optimize or replace quarantine without increasing rates of transmission *(8, 10, 37, 38)*;
- test certain essential workers such as firefighters and police officers to reduce or obviate the need for quarantine and minimize absenteeism *(10)*;

- deliver acceptable and feasible testing options and provide a sense of safety and well-being among students and workers in education settings (such as primary and secondary schools and universities) *(8, 39)*.

As with any testing for SARS-CoV-2, COVID-19 self-testing implementation needs to be strategic. The populations that may benefit from access to self-testing will vary widely by setting. Consequently, it is important for programmes and implementers to first review the latest epidemiology and local policies, consult communities and establish where and how self-testing implementation will be important. Community engagement and participation in planning and implementation will lead to more successful self-testing programming.

In any setting, COVID-19 self-testing should be considered as part of overall risk-based strategies and should not be implemented as a barrier or give the impression of increasing social inequalities in access to critical services. This is particularly relevant for educational settings with regard to accessing in-person learning, recreation and routine activities, especially for marginalized communities.

Costs and resources required by the health system and by individuals for COVID-19 self-testing need to be considered. In certain settings such as schools and workplaces, self-testing costs should not be borne by students or workers.

When introducing COVID-19 self-testing, programme managers may want to consider priority populations, such as health workers, or close contacts of confirmed SARS-CoV-2 cases. There may also be value in enabling access to COVID-19 self-testing in the community to enable personal choice, especially among populations most at risk of severe COVID-19 disease and those with greater challenges accessing existing testing services. Additional strategies for prioritizing COVID-19 self-testing may require more in-depth considerations and planning.

Box 3. WHO guidance on COVID-19 relevant to self-testing

For specific settings and populations:

- Preventing and mitigating COVID-19 at work;2021: https://www.who.int/publications/i/item/WHO-2019-nCoV-workplace-actions-policy-brief-2021-1
- Infection prevention and control guidance for long-term care facilities in the context of COVID-19 uptdate;2021: https://www.who.int/publications/i/item/WHO-2019-nCoV-IPC_long_term_care-2021.1
- Considerations for school-related public health measure in the context of COVID-19;2020: https://www.who.int/publications/i/item/considerations-for-school-related-public-health-measures-in-the-context-of-covid-19
- Key planning recommendations for mass gatherings in the context of COVID-19;2021: https://www.who.int/publications/i/item/10665-332235
- Holding gatherings during the COVID-19 pandemic;2021: https://www.who.int/publications/i/item/holding-gatherings-during-the-covid-19-pandemic-who-policy-brief-2-august-2021
- WHO guidance and training for health workers and administrators;2022: https://www.who.int/teams/risk-communication/health-workers-and-administrators
- Prevention, identification and management of health worker infection in the context of COVID-19; 2020: https://www.who.int/publications/i/item/10665-336265

For related guidance:

Surveillance and public health and social measures

- Public health surveillance for COVID-19: interim guidance; 2022: https://www.who.int/publications/i/item/WHO-2019-nCoV-SurveillanceGuidance-2022.1
- Critical preparedness, readiness and response actions for COVID-19; 2021: https://www.who.int/publications/i/item/critical-preparedness-readiness-and-response-actions-for-covid-19
- Considerations for implementing and adjusting public health and social measures in the context of COVID-19; 2021:https://www.who.int/publications/i/item/considerations-in-adjusting-public-health-and-social-measures-in-the-context-of-covid-19-interim-guidance

Contact tracing

- Contact tracing and quarantine in the context of the Omicron SARS-CoV-2 variant: interim guidance; 2022: https://www.who.int/publications/i/item/WHO-2019-nCoV-Contact-tracing-and-quarantine-Omicron-variant-2022.1
- Contact tracing in the context of COVID-19; 2021: https://www.who.int/publications/i/item/contact-tracing-in-the-context-of-covid-19
- Considerations for quarantine of contacts of COVID-19 cases; 2021: *https://www.who.int/publications/i/item/WHO-2019-nCoV-IHR-Quarantine-2021.1*

Infection prevention and control

- WHO infection prevention and control COVID-19 living guideline: mask use in community settings; 2021: https://app.magicapp.org/#/guideline/5962
- Infection prevention and control during health care when coronavirus disease (COVID-19) is suspected or confirmed; 2021: https://www.who.int/publications/i/item/WHO-2019-nCoV-IPC-2021.1
- Annex to Infection prevention and control during health care when coronavirus disease (COVID-19) is suspected or confirmed; 2021: https://www.who.int/publications/i/item/WHO-2019-nCoV-IPC-Annex-2021.1

Diagnostics and testing

- Interim guidance: Antigen-detection in the diagnosis of SARS-CoV-2 infection; 2021: https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays
- Recommendations for national SARS-CoV-2 testing strategies and diagnostic capacities; 2021: https://www.who.int/publications/i/item/WHO-2019-nCoV-lab-testing-2021.1-eng
- SARS-CoV-2 antigen-detecting rapid diagnostic tests: an implementation guide; 2020: https://www.who.int/publications/i/item/9789240017740
- COVID-19 Target product profiles for priority diagnostics to support response to the COVID-19 pandemic v.1.0; 2020: https://www.who.int/publications/m/item/covid-19-target-product-profiles-for-priority-diagnostics-to-support-response-to-the-covid-19-pandemic-v.0.1
- Diagnostic testing for SARS-CoV-2; 2020: https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2

Clinical management and therapeutics

- Therapeutics and COVID-19; 2022: https://www.who.int/teams/health-care-readiness/covid-19/therapeutics
- Clinical management of COVID-19; 2022: https://www.who.int/teams/health-care-readiness-clinical-unit/covid-19

Reporting and surveillance

COVID-19 self-testing use and test results may be integrated into existing reporting and surveillance mechanisms. A recent WHO survey found that in settings where COVID-19 self-testing result reporting was required, it was mostly for positive results only. There were, however, many respondents who noted no reporting requirements (Web Annex D). Digital tools to capture test results (with optional image collection) and/or enable reporting may be of use but need to be appropriately planned and adapted to the needs of end-users to be most successful. Community health workers, pharmacists, community groups and peer-led organizations may also play important roles in supporting monitoring of COVID-19 self-testing.

While data visibility may remain a limitation of self-testing implementation, increased testing access through COVID-19 self-testing has the potential to increase overall testing rates, which may help reduce transmission and increase overall well-being in the community. The aim of national surveillance for COVID-19 is to enable public health authorities to optimize intervention strategies to reduce transmission of SARS-CoV-2, thereby limiting associated morbidity and mortality *(17)*. Countries that use self-tests should consider how to best integrate reporting on self-testing into existing monitoring and surveillance efforts.

Research gaps and priorities

The GDG followed WHO guidance on setting research priorities *(40)* and identified several key areas for future research to inform implementation and scale-up decisions on COVID-19 self-testing (Box 4). For any self-testing research, it is important to partner with communities and a diverse group of stakeholders across a range of geographies, including low- and middle-income countries, to identify priorities and inform the design, implementation and monitoring of research efforts and outcomes.

Box 4. COVID-19 self-testing (C19ST) research priorities

Integration of COVID-19 self-testing with testing for other respiratory infections and/or with other health services

- What are the best approaches to incorporate COVID-19 self-testing with testing for other respiratory infections as part of differential diagnosis algorithms?
- What are the feasibility and impact of integrating COVID-19 self-testing with diagnostics for other respiratory infections?

Optimization of COVID-19 self-testing service delivery

- What are the most optimal, feasible and acceptable strategies for delivering C19ST, such as in-person, mail, online order, etc. to reach priority populations?
- What are the factors that affect results reporting and post-test actions?

Innovations with digital tools for COVID-19 self-testing

- How should digital tools, such as for result capture and linking with reporting systems, be utilized and optimized for monitoring and reporting C19ST implementation?
- How should digital tools be used to optimize service delivery and address challenges with effective implementation?

COVID-19 self-testing and surveillance

- What approaches can be used to incorporate C19ST into the national COVID-19 plan so that it contributes to overall surveillance efforts?
- What is the impact of variants on the performance of Ag-RDTs for both professional use and self-testing?

Resource use for COVID-19 self-testing

- What is the cost-effectiveness of C19ST across different epidemiological contexts (prevalence), target populations and testing frequencies compared to no additional testing or testing through the facility-based system?
- How can C19ST best be used to minimize the need for restrictions with macro-economic impacts, such as school and workplace closures and travel restrictions?

Process and methodology

In response to the needs of Member States and the availability of new evidence on COVID-19 self-testing, diverse stakeholders proposed the development of new WHO interim guidance for self-testing using SARS-CoV-2 Ag-RDTs. From October 2021 to February 2022, the WHO Department of Epidemic and Pandemic Preparedness and Prevention–supported by colleagues from the Global HIV, Hepatitis and Sexually Transmitted Infections programmes–led the development of this guidance with the independent Guideline Development Group on COVID-19 testing (GDG). This group is composed of 18 regionally representative external experts, including academics, researchers, programme managers, implementers and representatives of community networks and organizations. An internal steering committee and external peer review group also provided support. The Acknowledgements and Web Annex F provide the names of all meeting participants at the GDG meeting.

These guidelines were developed in accordance with procedures established by the WHO Publication Review Committee and Guidelines Review Committee *(41)*. Consistent with previous WHO guidelines, this guidance is based on a public health approach that considers effectiveness, values and preferences of end users, acceptability, feasibility, resource use and equity across a variety of settings. The systematic review findings and evidence-to-decision-making tables were prepared in accordance with the GRADE process *(29)*, and they were shared in advance and presented at the GDG meetings, where an independent methodologist facilitated the discussions. All Web Annexes are available on the WHO Website.

Limitations

There was low to moderate certainty evidence available on COVID-19 self-testing using SARS-CoV-2 Ag-RDTs. While supplementary evidence generated on values and preferences, resource-use, feasibility, policy and use in low- and middle-income countries provided critical information, research gaps and priorities were identified. It remains imperative for WHO to monitor the evidence on COVID-19 self-testing.

Plans for disseminating and updating

WHO Headquarters will work closely with WHO Regional and Country Offices and implementing partners to assist Member States to adapt the guidelines to their national context.

WHO will continue to monitor the situation closely for any changes that may affect this interim guidance. WHO will issue a further update to this guidance as evidence becomes available and is reviewed throughout 2022.

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Declaration of interests

All members of the GDG, non-WHO staff participating in meetings or guideline development and external peer reviewers submitted declarations of interest and confidentiality statements to the WHO secretariat. The WHO secretariat reviewed all declarations and found no conflicts of interest sufficient to preclude any GDG member from participating fully in the development of the guidelines. Web Annex F provides a full summary.

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Web annexes

Web Annex A. GRADE table: Should COVID-19 self-testing, using SARS-CoV-2 Ag-RDTs, be offered as an additional approach?

Web Annex B. Multi-country feasibility studies on COVID-19 self-testing using SARS-CoV-2 Ag-RDTs

Web Annex C. Multi-country study of values and preferences on COVID-19 self-testing using SARS-CoV-2 Ag-RDTs

Web Annex D. Global survey on COVID-19 self-testing using SARS-CoV-2 Ag-RDTs

Web Annex E. Evidence to decision making table: Should COVID-19 self-testing, using Ag-RDTs, be offered as an additional testing approach?

Web Annex F. Declarations of interest for the Guideline Development Group, Observers and Peer Reviewers

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