

Laboratory testing strategy recommendations for COVID-19

Interim guidance
21 March 2020



Background

WHO has published [laboratory testing guidance for COVID-19 in suspected human cases](#). Recognizing that the global spread of COVID-19 has dramatically increased the number of suspected cases and the geographic area where laboratory testing needed to be implemented, intensified COVID-19 molecular testing has led to shortages of molecular testing reagents globally for COVID-19 and for other molecular diagnostics. Beyond supply issues, there are significant limitations of absorption capacity in many regions, especially in low- and middle-income countries.

As part of the [Strategic Preparedness and Response Plan](#), WHO developed testing strategy recommendations. The foundation of this strategy is threefold:

- All countries should increase their level of preparedness, alert, and response to identify, manage, and care for new cases of COVID-19; laboratory testing is an integral part of this strategy.
- Countries should prepare to respond to different public health scenarios, recognizing that there is no one-size-fits-all approach to managing cases and outbreaks of COVID-19.
- Each country should assess its risk and rapidly implement the necessary measures at the appropriate scale and prepare for a testing and [clinical care](#) surge to reduce both COVID-19 transmission and economic, public health, and social impacts.

Good laboratory practices that produce accurate results are key to assure that laboratory testing benefits the public health response. The availability of timely and accurate results can be threatened when testing demands outstrip capacity, such as when:

- there is a backlog for testing and it is no longer possible to turn around results within 24 to 48 hours
- the demand for laboratory reagents exceeds the capacity for supply
- laboratory staff are exhausted and working hours need to be reduced
- the number of incoming samples exceeds the capacity for safe pretesting storage
- critical staff become infected or are otherwise unable to perform their duties (e.g. being in quarantine)
- laboratory instruments can no longer be serviced or properly maintained.

Some of these constraints can be overcome by a proper risk assessment in the early phase of an outbreak and preventive solutions put in place in advance.

Purpose of the document

Depending on the intensity of transmission, the number of cases and laboratory testing and surge capacity, it may be necessary to prioritize who gets tested according to health objectives.

WHO has outlined [critical priority actions for preparedness, readiness, and response actions for COVID-19](#) and has defined four transmission scenarios:

1. Countries with no cases (No Cases);
2. Countries with 1 or more cases, imported or locally detected (Sporadic Cases);
3. Countries experiencing clusters of cases related in time, geographic location, or common exposure (Clusters of cases);
4. Countries experiencing larger outbreaks or sustained and pervasive local transmission (Community transmission).

This document provides guidance to policy makers and laboratories on testing strategies for each of these four scenarios, including the scenario in which testing can be performed only on a limited number of patients. See Table 1 for summary of testing strategies for each phase.

As the COVID-19 situation evolves, the outbreak characteristics a country faces will change. Countries could experience one or more of these scenarios at the sub-national level and should adjust and tailor their approach to the local context and prepare for potential subsequent phases. As the transition from sporadic cases to community transmission can be extremely rapid, WHO strongly advises all countries to prepare even before the first case has been detected.

Preparedness and readiness should include the establishment of COVID-19 testing capacity in country. If testing capacity is not yet available, assess preparedness for sending specimens of suspected cases to a WHO reference laboratory for COVID-19 testing while establishing local testing capacity. If testing is available at the national level, plan for surge capacity by establishing decentralized testing capacity in sub-national laboratories under the supervision of the COVID-19 national reference laboratory. Options to engage private laboratory services or the academic sector should be considered. When testing facilities are limited, available facilities tend to be located in or near a capital city, making timely access to testing difficult for people living in other parts of the country. Consider the possibility of mobile laboratories or, if available, automated integrated NAAT systems that can be operated in remote regions and by staff with minimal training.

Always ensure that staff are well trained in [biosecurity](#) and the required technical skills to perform the work. Ensure

access to specimen collection materials, packaging materials, reagents, supplies, and laboratory protocols.

This document focusses solely on molecular testing as this is the current recommended method for the identification of infectious cases. The technical requirements for molecular testing are included in: [Laboratory testing for COVID-19 in suspected human cases](#). Serological assays will play an important role in research and surveillance but are not currently recommended for case detection and are not included in this document. The role of rapid disposable tests for antigen detection for COVID-19 needs to be evaluated and is not currently recommended for clinical diagnosis pending more evidence on test performance and operational utility. WHO will update this guidance as more information laboratory tests for COVID-19 becomes available.

Considerations for countries that have not yet reported cases (no cases transmission scenario)

WHO recommends that all suspect cases be tested for COVID-19 according to WHO case definitions (see: [Global Surveillance for human infection with coronavirus disease \(COVID-19\)](#)). Demonstrating that COVID-19 is not circulating in a given population requires adequate surveillance. A surge in severe acute respiratory infections (SARI) or influenza-like illness (ILI) observed through clinical surveillance can be a sign of unrecognized COVID-19 circulation in the general population and should prompt specific testing for COVID-19. It is important to stress that not having laboratory-confirmed cases does not imply that a country is free from COVID-19, and can be a sign of insufficient testing and surveillance. All countries are encouraged to critically assess surveillance and respiratory syndrome testing strategies. WHO encourages countries to report SARI/ILI data through GISRS and is developing Interim operational considerations for COVID-19 surveillance using GISRS.

An assessment of possible risk areas and populations (e.g. related to travel to high-risk countries) may require a more intensified testing strategy. Medical professionals should also be alert and request testing when encountering patients with unexpected clinical presentation or when there is an increase in hospital admissions in a specific demographic group. Even before any COVID cases have been detected nationally, it is critical to prepare for the possibility of increasing transmission and plan for surge COVID-19 testing capacity.

Considerations for countries dealing with sporadic cases

WHO recommends that all suspected cases be tested for COVID-19 according to WHO case definitions (see: [Global Surveillance for human infection with coronavirus disease \(COVID-19\)](#)). When the first case of COVID-19 is detected in a country, [investigations should be carried out to determine the source of the infection](#) (e.g. imported case, local human transmission, or possible animal-to-human transmission). This investigation may include genetic sequencing of the newly detected virus where feasible. It is recommended that

the detection of a first case be confirmed by one of the [WHO COVID-19 Reference Laboratories](#). All other recommendations listed in the no-case scenario above still apply; however, each sporadic case requires aggressive and active case finding, isolation and care, and comprehensive contact tracing and [quarantine](#).

Considerations for countries dealing with clusters of cases

WHO recommends that all suspected cases be tested for COVID-19 according to WHO case definitions (see: [Global Surveillance for human infection with coronavirus disease \(COVID-19\)](#)). All recommendations in the previous two transmission scenarios remain applicable, including [Considerations in the investigation of cases and clusters of COVID-19](#). Plans should be adopted to improve national testing capacity, as needed, and assess the effectiveness of the laboratory network. Intensify investigation of cases and clusters and SARI/ILI surveillance.

When clusters become large, it is critical that testing of suspected cases continues so that cases can be isolated, contacts can be quarantined, and chains of transmission can be broken.

Considerations for countries dealing with community transmission

Faced with community transmission over large areas of the country, laboratories will need to be prepared for the significant increase in the number of specimens that need to be tested for COVID-19. Testing constraints should be anticipated, and prioritization will be required to assure the highest public health impact of reducing transmission using available resources.

Prioritized testing strategies

As the virus does not respect borders, a country can simultaneously have areas with no cases and areas with community circulation. Thus, different testing strategies might be needed within the same country.

For areas within a country with no circulation, the objectives remain to test all suspected cases in an effort to detect first cases in new areas or settings as rapidly as possible, and take immediate measures to prevent (further) spread in that region.

Testing in areas with community transmission and in settings where testing capacity cannot meet needs must be prioritized. This prioritization should focus on the early identification and protection of vulnerable patients and health care workers. Focused testing in health care facilities ensures that infection prevention and control measures can be correctly implemented such that vulnerable patients who do not have COVID are protected from nosocomial COVID-19 infection. Testing among vulnerable populations and risk groups will be important for early treatment to minimize progression to severe disease. Results of testing of specific populations (e.g. patients requiring hospitalization for respiratory disease) can give a rough estimate of the size of the outbreak in the area and be used to monitor trends.

In the setting of limited resources in areas with community transmission, prioritization for testing should be given to:

- people who are at risk of developing severe disease and vulnerable populations, who will require hospitalization and advanced care for COVID-19 (see [Clinical management of severe acute respiratory infections when novel coronavirus is suspected](#)).
- health workers (including emergency services and non-clinical staff) regardless of whether they are a contact of a confirmed case (to protect health workers and reduce the risk of nosocomial transmission)
- the first symptomatic individuals in a closed setting (e.g. schools, long-term living facilities, prisons, hospitals) to quickly identify outbreaks and ensure containment measures. All other individuals with symptoms related to the close settings may be considered probable cases and isolated without additional testing if testing capacity is limited.

Table 1: Considerations for laboratory testing for each transmission scenario*

	No Cases	Sporadic Cases	Clusters of Cases	Community Transmission
Transmission scenario	No reported cases	One or more cases, imported or locally acquired	Most cases of local transmission linked to chains of transmission	Outbreaks with the inability to relate confirmed cases through chains of transmission for a large number of cases, or by increasing positive tests through sentinel samples (routine systematic testing of respiratory samples from established laboratories)
Public health aim	Stop transmission and prevent spread	Stop transmission and prevent spread	Stop transmission and prevent spread.	Slow transmission, reduce case numbers, end community outbreaks
Testing strategy guidance documents	<p>Test all individuals meeting the suspected case definition</p> <p>Test a subset of samples from SARI/ILI surveillance for COVID-19</p> <p>Test patients with unexpected clinical presentation or an increase in hospital admissions in a specific demographic group that could be COVID-19</p>	<p>Test all individuals meeting the suspected case definition</p> <p>Considerations in the investigation of cases and clusters of COVID-19</p> <p>Clinical management of severe acute respiratory infections when novel coronavirus is suspected.</p> <p>SARI/ILI surveillance for COVID-19 and reporting: see Interim operational guidance for COVID-19</p>	<p>Test all individuals meeting the suspected case definition</p> <p>Considerations in the investigation of cases and clusters of COVID-19.</p> <p>Clinical management of severe acute respiratory infections when novel coronavirus is suspected.</p> <p>SARI/ILI surveillance for COVID-19 and reporting: see Interim operational guidance for COVID-19</p>	<p>If diagnostic capacity is insufficient, implement prioritized testing and measures that can reduce spread (e.g. isolation), including:</p> <ul style="list-style-type: none"> people who are at risk of developing severe disease and vulnerable populations, who will require hospitalization and advanced care for COVID-19 (see Clinical management of severe acute respiratory infections when novel coronavirus is suspected). health workers (including emergency services and non-clinical staff) regardless of whether they are a contact of a confirmed case (to protect health workers and reduce the risk of nosocomial transmission) the first symptomatic individuals in a closed setting (e.g. schools, long term living facilities, prisons, hospitals) to quickly identify outbreaks and ensure containment measures

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