Laboratory testing strategy recommendations for COVID-19

Interim guidance
22 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 biosafety 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-19 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 reference laboratories providing confirmatory testing for COVID-19. All other recommendations listed in the *no cases* scenario above still apply, however each sporadic case requires active case finding of contacts and the implementation of isolation and care as needed (see Considerations in the investigation of cases and clusters of COVID-19.

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.

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. Planning should include preservation of critical laboratory testing for other diseases and essential surveillance activities.

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 must be rationalized in areas with community transmission and where testing capacity cannot meet needs. Priority should be given to the detection and protection of vulnerable patients and health care workers. Focused testing in health care facilities assures infection prevention and control measures can be correctly implemented and vulnerable non COVID-19 patients are protected from

nosocomial COVID-19 infection. If therapeutics become available this will also have implications for testing, as suspected patients that would be eligible for therapy should be identified. 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).
- symptomatic 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. Reduce health, social and economic impact of the outbreak. Minimize disruptions in health care for non-COVID-19 illness.
Testing strategy guidance documents	Test all individuals meeting the suspected case definition Test a subset of samples from SARI/ILI surveillance for COVID-19 Test patients with unexpected clinical presentation or an increase in hospital admissions in a specific demographic group that could be COVID-19	Test all individuals meeting the suspect case definition Considerations in the investigation of cases and clusters of COVID-19 Clinical management of severe acute respiratory infections when novel coronavirus is suspected. SARI/ILI surveillance for COVID-19 and reporting: see Interim operational considerations for COVID-19 surveillance using GISRS.	Test all individuals meeting the suspected case definition Considerations in the investigation of cases and clusters of COVID-19. Clinical management of severe acute respiratory infections when novel coronavirus is suspected. SARI/ILI surveillance for COVID-19 and reporting: see Interim operational considerations for COVID-19 surveillance using GISRS.	If diagnostic capacity is insufficient, implement prioritized testing and measures that can reduce spread (e.g. isolation)., including: • 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). • symptomatic 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

*In all scenarios, if feasible, test for treatable diseases (according to local protocols)

Management of diagnostic and clinical resources may change in the face of severe shortages of diagnostic tests or reagents.

Below are examples of how specific situations might be managed in such a setting.

Table 2. Example situations and management alternatives if testing capacity is overwhelmed

Situation	Alternatives if system is overwhelmed and testing is not possible
Suspected case, mild, with no risk factors	Register as a suspected case, home isolate according to WHO guidelines, and do not test
Suspected case requiring admission in health care facility regardless of severity	Strongly recommended to test. If testing is not possible, implement isolation measures warding against nosocomial transmission (thus no cohort isolation possible); test and treat other possible causes according to local guidelines.
Symptomatic health care worker identified as a contact	Strongly recommended to test
Symptomatic health care worker with no known COVID-19 contact	In areas with COVID-19 community transmission, test
Increased number of suspected cases in a specific demographic group (potential cluster)	Test a subset of the suspects
Closed settings, including schools, hospitals, long term living facilities	Test initial cases. Consider all other symptomatic individuals as probable cases
Recovering patient test-negative twice	If clinically recovered, discharge after an additional 14 days in self-isolation
Contact tracing in areas of community transmission	Quarantine contacts for 14 days, in lieu of testing. If symptomatic, assume COVID-19 and extend quarantine
Patients hospitalized for severe disease in setting with no testing capacity	Consider as suspected case and take precautions as if COVID-19 positive, treat for treatable local diseases

Alternative measures that can reduce spread if prioritized testing needs to be implemented

Prioritization of testing does not preclude interventions to prevent further spread. Some examples of alternative measures that can be taken when testing needs to be prioritized are listed in Table 2. In each individual setting, the most appropriate measures need to be formulated for that specific setting. As some of these measures can have a great impact on all aspects of life and society they need to be weighed and a risk assessment at individual and societal level needs to be performed. Ensure that the community is informed of expectations for behaviour and care-seeking needs for COVID-19.

Tracking testing indicators

Countries should track the quantity and results of testing and consider reporting to WHO. Indicators could include the number of SARI/ILI cases reported (compared with previous years in same month/week), the number of patients tested for COVID-19, the number of patients who test positive for COVID-19, the number of tested suspected cases per 100,000 population, and the number of ICU admissions for COVID-19.

WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 2 years after the date of publication.

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