

An update on
Testing strategies for COVID-19

THE LATEST ON THE COVID-19 GLOBAL SITUATION
& HOW TO USE TESTING TO ACHIEVE PUBLIC HEALTH MEASURES

Testing should be linked to public health goals

- **COVID-19 testing is part of a comprehensive strategy to:**
 - Suppress SARS-CoV-2 transmission
 - Prevent severe disease and reduce mortality
 - Protect the health system
- **Testing should be linked to public health actions such as:**
 - Clinical care
 - Isolation of confirmed cases
 - Contact tracing
 - Supported quarantine of contacts
 - Providing information to the person being tested

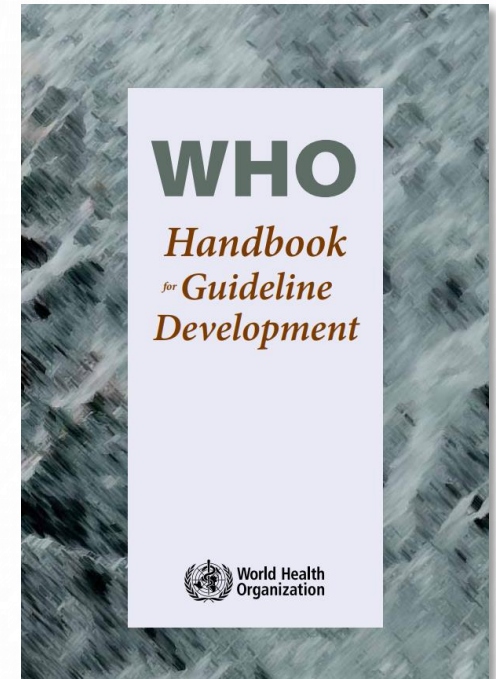
You cannot fight a fire blindfolded. And we cannot stop this pandemic if we don't know who is infected.

Tedros Adhanom Ghebreyesus
Director-General, World Health Organization
16 March 2020



Developing WHO guidance on testing strategies

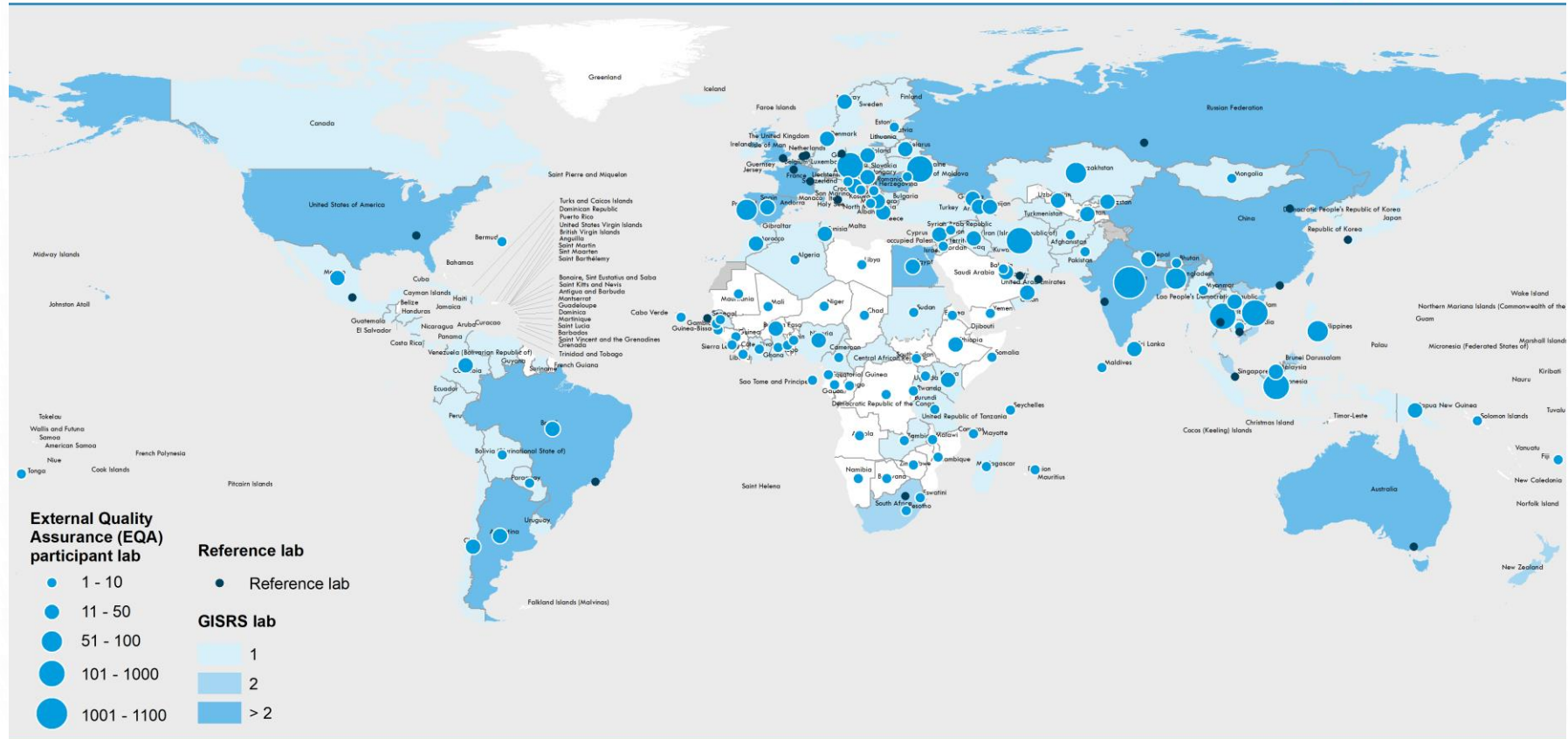
- WHO draws upon **internal expertise across all 3 levels of the organization – HQ, regional and country offices**, and leverages the different levels to engage stakeholders:
 - Convening and coordinating partners, expert groups and Member States
 - Enhancing information sharing among and from MS such as challenges and lessons learnt
- WHO draws upon **external expertise through its reference laboratory networks, members of the ACT-Accelerator, including civil society, and open forums** including global consultations
- WHO closely monitors literature for updates and scientific developments
- A **Guideline Development Group is being established**, according to WHO procedures: <https://apps.who.int/iris/handle/10665/145714> to prioritize evidence reviews pertaining to SARS-CoV-2 diagnostics and diagnostic testing strategies.
 - Will include membership of civil society



Drawing on external expertise through laboratory networks



COVID-19 lab network



Data Source: World Health Organization.
 Map Production: WHO Health Emergencies Programme
 Request ID: COVID19_45

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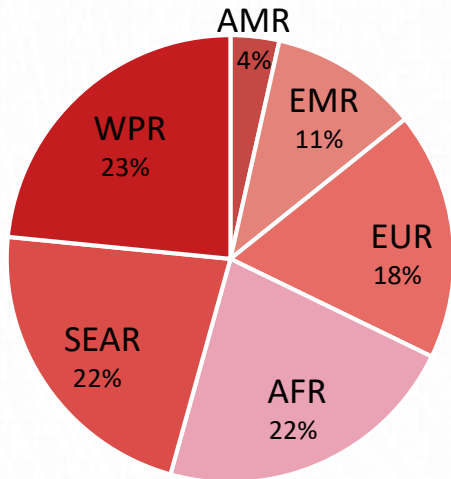
The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement. [1] All references to Kosovo in this document should be understood to be in the context of the United Nations Security Council resolution 1244 (1999).

The laboratory Community of Practice

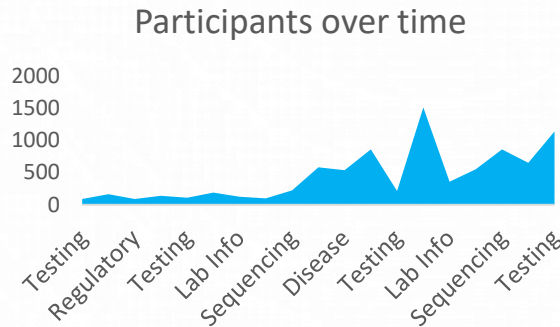


Participation

7763 participants from **182** countries



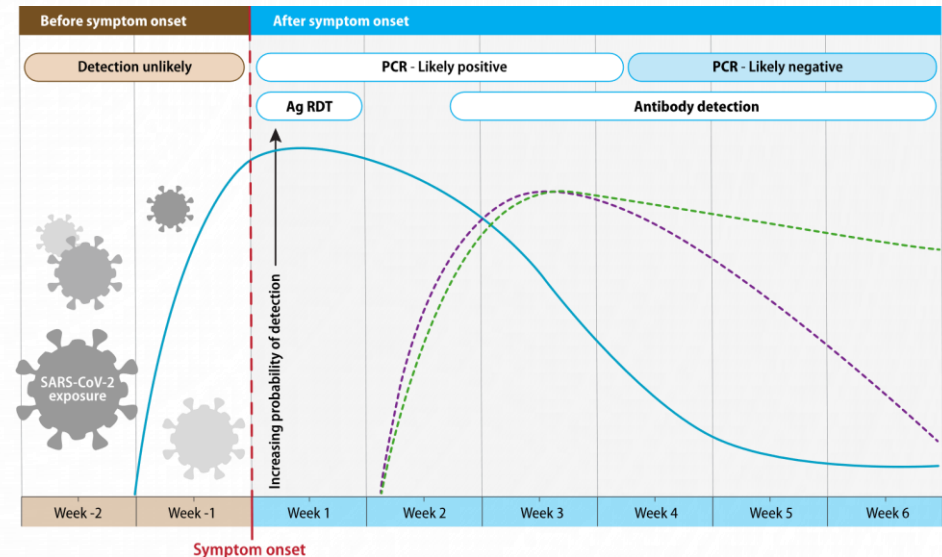
Percentage of participants from each region



- WHO established the CoP in March 2020 and leverages this network to reach lab stakeholders from 1700+ places of work including Ministries of Health, research institutions, NGOs and private industry
- 20 webinars have been given on topics such as testing, biosafety and sequencing, provided live in EN, FR, RU and PT
- High engagement with over 800 people attending more than one session

Individual factors can contribute to SARS-CoV-2 transmission

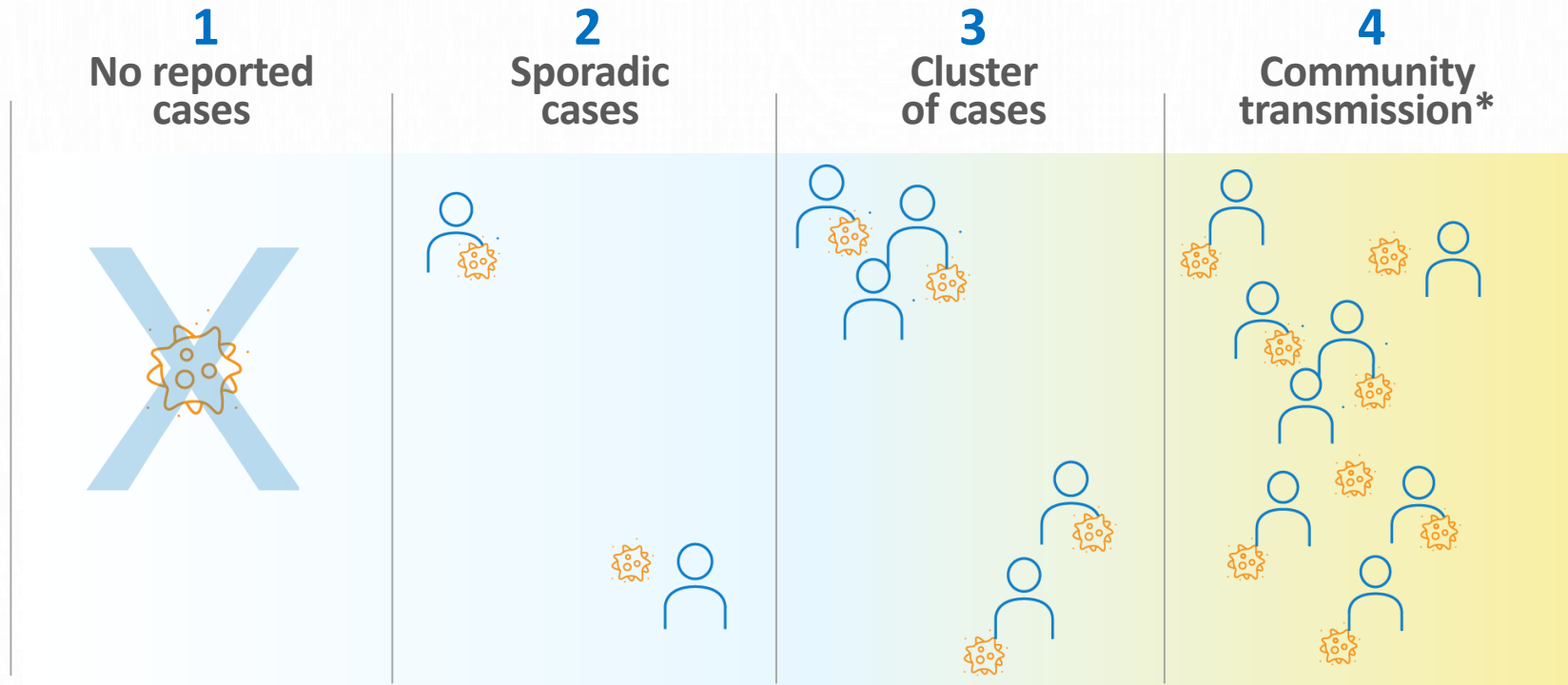
- People infected with SARS-CoV-2 can transmit virus with or without symptoms
- Most infected people transmit the virus around 2 days before they develop symptoms and up to 9-10 days after symptom onset
- People who develop severe disease can be infectious for longer
- Immunocompromised people can shed the virus for months
- Symptomatic persons infected with SARS-CoV-2 are 3 to 18 times more likely to transmit the virus than asymptomatic persons*



* https://cdn.who.int/media/docs/default-source/epi-win/covid_update-31-may-2021.pdf?sfvrsn=32d0b8d6_4

COVID-19 testing strategies depend on the transmission scenario

Four different scenarios



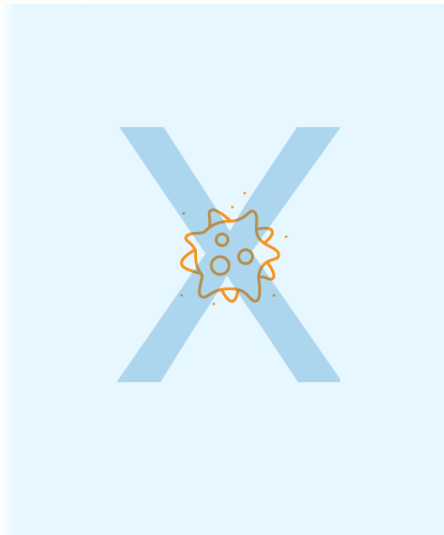
*Countries can experience one or more of these scenarios at the same time in different places

<https://www.who.int/publications/i/item/considerations-in-adjusting-public-health-and-social-measures-in-the-context-of-covid-19-interim-guidance>

Testing strategy when there are no cases

Transmission scenario “No cases”: no reported cases

No
cases



Scenario 1

Testing strategy scenario 1:

- Aim to: Detect imported cases early to prevent clusters
- Use a RT-PCR* test to confirm the first cases**
- Be vigilant, maintain testing capacity at a minimum, but surge capacity as a precaution
- Ensure robust surveillance activities continue

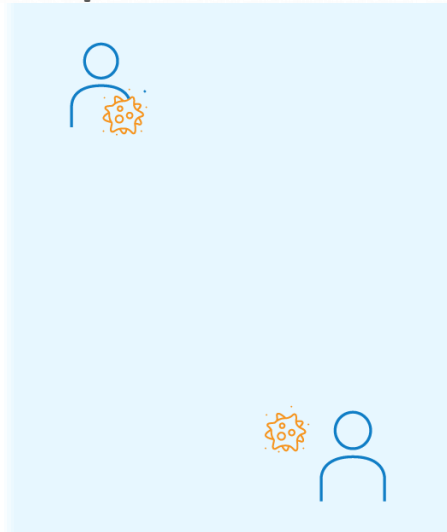
** <https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2>
<https://www.who.int/publications/i/item/WHO-2019-nCoV-lab-testing-2021.1-eng>

*RT-PCR or Nucleic Acid Amplification Test (NAAT) is the reference test

Testing strategy when there are sporadic cases

Transmission scenario “Sporadic cases”: cases detected in the last 14 days are imported, sporadic or linked to imported/sporadic cases and there are no clear signals of further transmission*

Sporadic cases



Scenario 2

Testing strategy scenario 2:

- Aim to: Prevent onward SARS-CoV-2 transmission through case finding:
 - Test symptomatic persons and asymptomatic contacts of confirmed or probable cases
 - Treat and isolate persons with confirmed or probable SARS-CoV-2 infection
 - Trace contacts of confirmed or probable cases
- Use a RT-PCR* test**

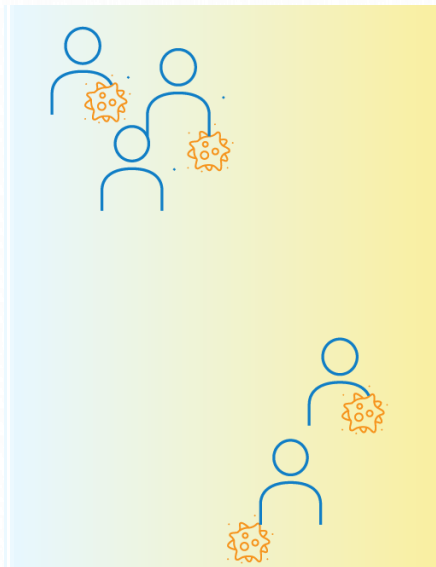
** <https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2>
<https://www.who.int/publications/i/item/WHO-2019-nCoV-lab-testing-2021.1-eng>

*RT-PCR or Nucleic Acid Amplification Test (NAAT) is the reference test

Testing strategy when there are clusters of cases

Transmission Scenario “Clusters of cases”: cases detected in the last 14 days are predominantly limited to well-defined clusters

Clusters of cases



Scenario 3

Testing strategy scenario 3

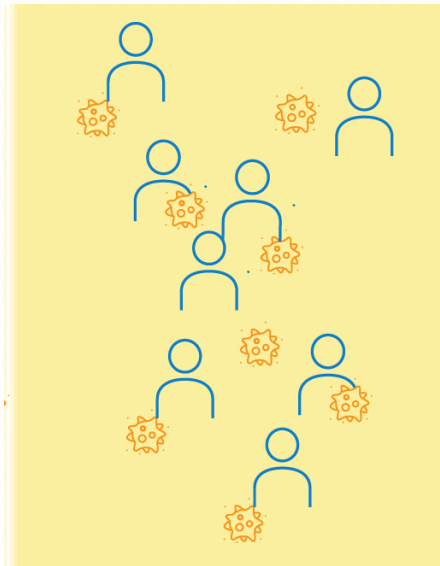
- Aim to: Prevent onward SARS-CoV-2 transmission through case finding:
 - Test symptomatic persons and asymptomatic contacts of confirmed cases
 - Treat and isolate persons with confirmed SARS-CoV-2 infection
 - Trace contacts of symptomatic persons
- Important to carry out outbreak and cluster investigations
 - Confirm suspected outbreaks of COVID-19 among symptomatic persons
- Use a RT-PCR test when available*

* <https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2>
<https://www.who.int/publications/i/item/WHO-2019-nCoV-lab-testing-2021.1-eng>

Testing strategy when there is community transmission

Transmission scenario “Community transmission”: high incidence of locally acquired, widely dispersed cases in the past 14 days

Community transmission



Scenario 4

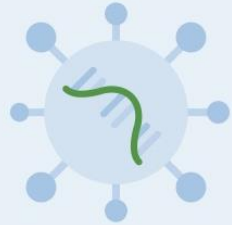
Testing strategy scenario 4:

- Aim to: Prevent onward SARS-CoV-2 transmission as much as possible through case finding:
 - Test symptomatic persons
 - Test asymptomatic contacts of confirmed **or probable** cases if capacity allows
 - Treat and isolate persons with confirmed **or probable** SARS-CoV-2 infection
 - Trace contacts of symptomatic persons*
- Important to carry out outbreak investigations, especially in vulnerable groups or in areas where there can be superspreading events
 - Confirm suspected outbreaks of COVID-19 among symptomatic persons
- If there is limited testing capacity, prioritize testing of **suspected COVID-19 cases** who are:
 - Persons at risk of developing severe disease
 - Health workers
 - Inpatients in health facilities
 - in a closed settings such as a school, prison or long-term living facility
- Use a RT-PCR test or an antigen rapid diagnostic test (RDT)*

* In settings of widespread community transmission, an Ag-RDT can be used

SARS-CoV-2 diagnostic tests

Types of tests:



Nucleic acid amplification testing

Detects **genetic material** of the virus

Uses **upper respiratory specimens*** to diagnose **acute SARS-CoV-2 infection**.

Nucleic acid amplification testing (NAAT), for example RT-PCR, is the **reference method for detection of acute SARS-CoV-2 infection**.

Results: usually available **within 24 hours**. Testing takes 30 minutes to 4 hours (depending on the test), but transport to the testing laboratory can add hours to days.



Antigen

Detection rapid diagnostic testing – detects **viral protein(s)**

Uses **upper respiratory specimens*** to diagnose **acute SARS-CoV-2 infection**.

Performance is best within first 5-7 days of symptoms.

Results: within 15-30 minutes, not requiring laboratory infrastructure.



Antibody testing

Detects **antibodies** against the virus

Uses **serum/plasma or whole blood specimens** to detect antibodies generated by **prior SARS-CoV-2 infection or vaccination**.

SARS-CoV-2 antibodies are usually detectable 1-2 weeks after infection or vaccination.

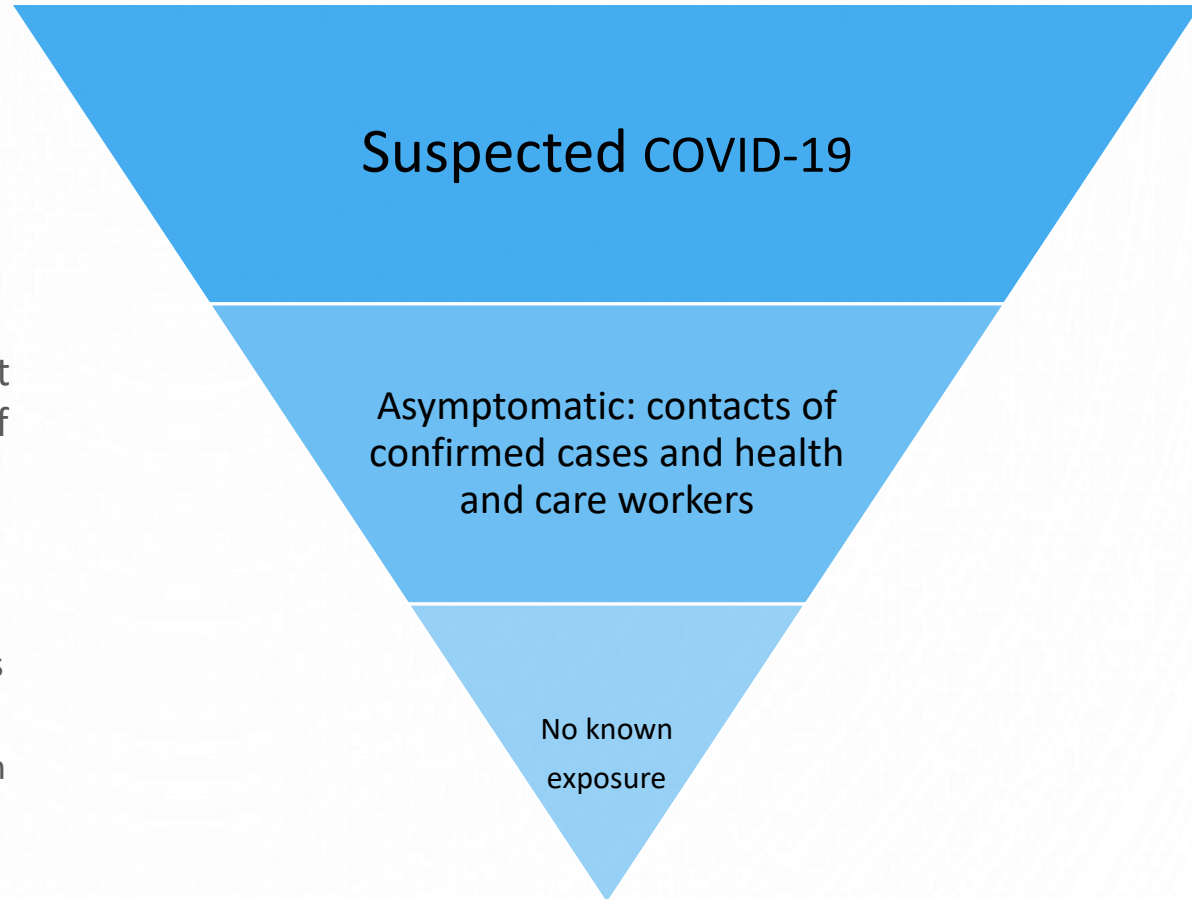
Results: **within 24 hours**; point of care tests within 10-30 mins.

- Countries need to test for SARS-CoV-2 according to the national strategy, using available and approved diagnostic tests
- WHO recommends testing of all SARS-CoV-2 suspected cases
- More information on diagnostic testing can be found here: <https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2>
- More information on use of Ag-RDTs can be found here: <https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2-infection-using-rapid-immunoassays>
- More information on testing strategy recommendations can be found here: <https://www.who.int/publications/i/item/WHO-2019-nCoV-lab-testing-2021.1-eng>

*Some NAA tests and some Ag-RDTs are designed to work on upper respiratory track samples or saliva
For more information: https://www.youtube.com/watch?v=PhdSdJu_QXI

How should testing be prioritized ?

- WHO recommends that all individuals who are suspected to be infected with SARS-CoV-2 be tested with NAAT or Ag-RDT, regardless of vaccination status or COVID-19 disease history
- Asymptomatic individuals should be tested with NAAT or Ag-RDT if they are at **higher** risk of SARS-CoV-2 infection and if resources are available to test them
- Individuals at **higher** risk of SARS-CoV-2 infection include:
 - Contacts of confirmed or probable cases
 - People who are frequently exposed through their occupation, such as health and care workers or long-term care facility workers who are providing care to COVID-19 patients



How should testing be prioritized?

- In some countries or settings, there aren't enough resources to test everyone who meets the suspected case definition
- In these situations, the following people should be prioritized for testing:
 - People at a higher risk of developing severe disease
 - Health and care workers
 - Inpatients in health facilities
 - The first symptomatic individuals in a closed setting
- It is also important to expand and decentralize capacity to improve access to testing
- This can be done through expanding the laboratory network or by introducing more point of care tests such as Ag-RDTs



Photo: WHO

Use of Ag-RDTs

- NAAT-RT-PCR is the reference standard. High quality Ag-RDTs helps to increase access to testing and support outbreak response, especially outside of lab and clinical settings
- Some Ag-RDTs have attained WHO Emergency Use Listing
- Based on published data Ag-RDT results will be most reliable during the first 5-7 days after onset of symptoms and when SARS-CoV-2 prevalence is $\geq 5\%$
- Shelf life (12 months) and storage conditions (max 30°C) will pose challenges for supply chains in many settings
- End-users should be trained @ WHO/FIND have provided trainings
- Confirmatory testing by NAAT is not required, but should be considered based on the clinical history, presentation and epidemiological context

Use of antigen-detection rapid diagnostic testing

WHO recommends that all suspected cases be tested for SARS-CoV-2



Antigen-detection diagnostic testing

Uses upper respiratory specimen or saliva to test for SARS-CoV-2 infection by detecting viral proteins (e.g. nucleoprotein).

Can be used outside of clinical and laboratory settings, including in communities (*)

Antigen-detection rapid diagnostic tests (Ag-RDT), with adequate performance ($\geq 80\%$ sensitivity and $\geq 97\%$ specificity compared to a NAAT reference assay) are easy to use, can rapidly detect SARS-CoV-2 infection and do not require laboratory infrastructure.

HOW, WHEN, WHERE:

Ag-RDTs are used to detect acute SARS-CoV-2 infection and are best used for:

1

CASE FINDING

As a **primary case-detection tool** for testing all suspected cases.

Can be used to detect SARS-CoV-2 in many settings including in health facilities, testing centers, care homes, prisons, schools, communities where there is ongoing transmission.

2

CONTACT TRACING

To **identify infection among asymptomatic contacts of cases** (1)

3

OUTBREAK INVESTIGATIONS

To **confirm suspected outbreaks of COVID-19** among symptomatic individuals, especially in closed or semi-closed settings including schools, care-homes, cruise ships, prisons, work-places and dormitories, etc

4

MONITOR TRENDS

To **monitor trends in disease incidence in communities**, and particularly among frequently exposed workers, including health and care workers, irrespective of symptoms.

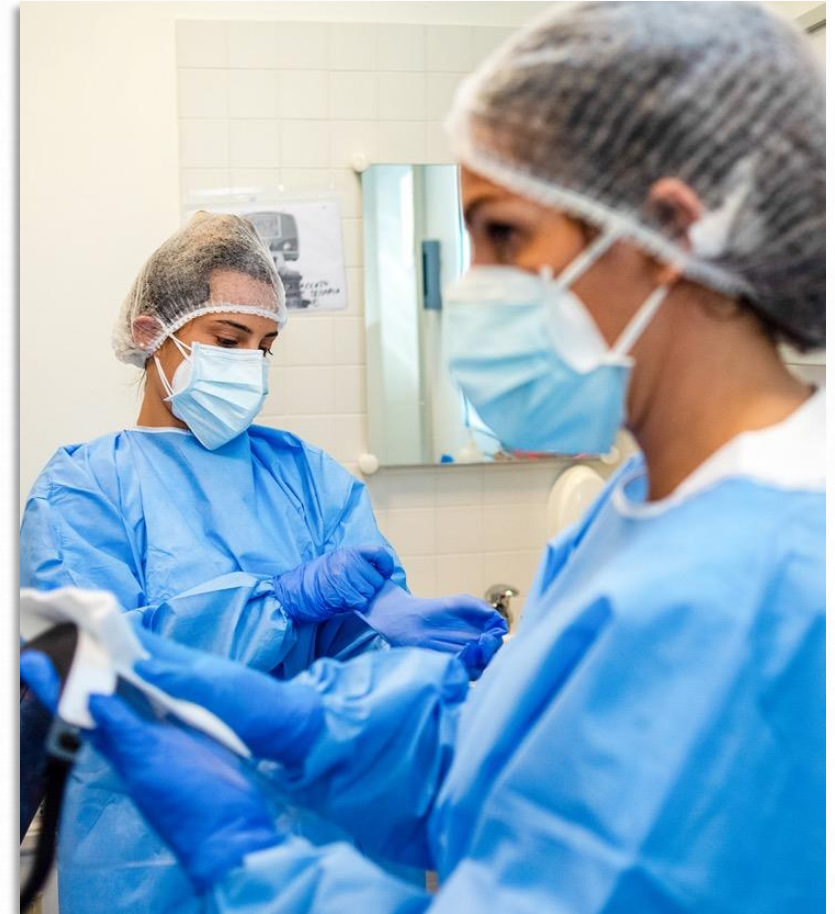
*AgRDT testing should be performed by trained individuals. WHO training materials can be found here: <https://extranet.who.int/hstpl/content/sars-cov-2-antigen-rapid-diagnostic-test-training-package>

¹ Ag-RDTs can be used to test asymptomatic contacts of confirmed cases, even if the Ag-RDT is not specifically authorized for this use.

For more information see WHO guidance September 2020 <https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2-infection-using-rapid-immunoassays>

Protecting the health system

- **Health and care workers** account for around **7.7% of COVID-19 cases** reported to WHO¹
- Health and care workers can be infected with SARS-CoV-2 while at their work or at the community level
- Those caring for COVID-19 patients are considered at a higher risk of being infected, therefore should be considered for testing, even if asymptomatic
- **Testing is a key strategy**
 - To treat and isolate cases when positive
 - To reduce the risk of transmission to patients, co-workers, visitors and their contacts outside the health facility

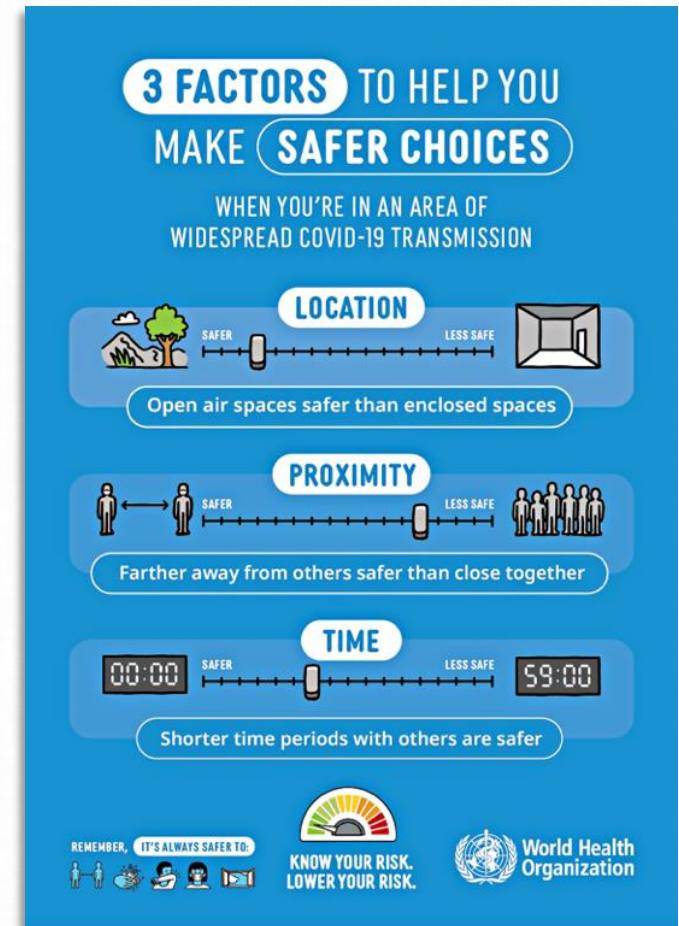


Source: WHO

¹ global case-based and weekly aggregate surveillance data collected by WHO
<https://www.who.int/news/item/17-09-2020-keep-health-workers-safe-to-keep-patients-safe-who>
<https://www.who.int/publications/i/item/10665-336265>

SARS-CoV-2 testing strategies in settings with an increased risk of transmission*

- A higher-risk setting is any place where SARS-CoV-2 spreads more easily, such as poorly ventilated spaces or crowded indoor settings where people tend to spend longer periods of time
- Higher risk settings include schools, workplaces, prisons, long-term living facilities and settings where people gather for long periods of time
- **Recommended testing strategy:**
 - Persons showing any symptoms should isolate
 - Test symptomatic persons, asymptomatic contacts of confirmed cases, and people caring for COVID-19 patients including health workers and long term care facility workers
 - Treat and isolate persons with confirmed SARS-CoV-2 infection
 - If there is limited testing capacity, testing symptomatic persons in settings with an increased risk of transmission should be prioritized
- **Widespread testing of asymptomatic individuals** is currently **not recommended** due to the significant costs associated with it and the lack of data on its effectiveness
- **Use public health and social measures to limit transmission**

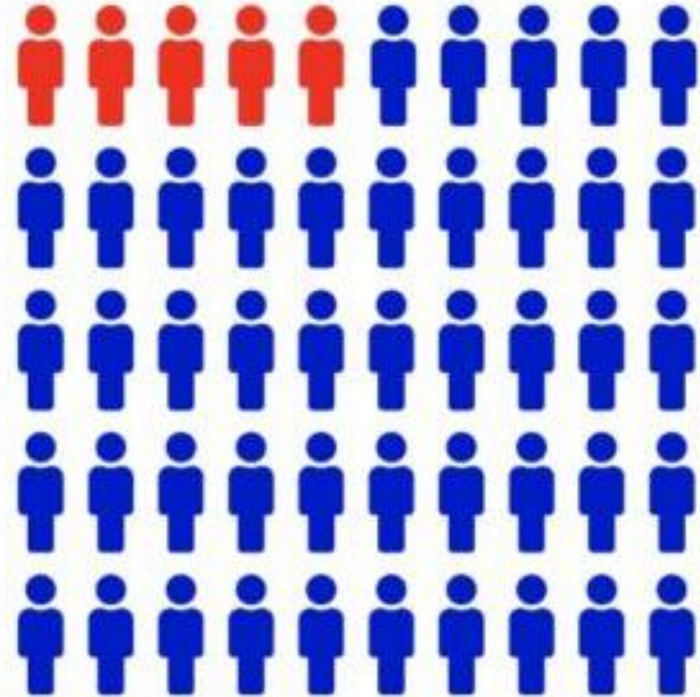


* Outside health facilities

<https://www.who.int/publications/i/item/WHO-2019-nCoV-lab-testing-2021.1-eng>

Transmission scenarios influence the predictive values of SARS-CoV-2 testing

- The different SARS-CoV-2 transmission scenarios affect the positive and negative predictive values of SARS-CoV-2 tests
 - **Positive predictive value** is the probability that persons with a **positive test truly have the disease**
 - **Negative predictive value** is the probability that persons with a **negative test truly don't have the disease**
- A SARS-CoV-2 test may have a poor positive predictive value (a high number of false positives) when used in a community where prevalence of SARS-CoV-2 is low
- Therefore, **in populations with few or no cases, it is preferable to use the reference NAAT to diagnose cases**, as it better correctly identifies persons without COVID-19



** <https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2>
<https://www.who.int/publications/i/item/WHO-2019-nCoV-lab-testing-2021.1-eng>

Source: <https://www.statnews.com/2020/03/31/covid-19-overcoming-testing-challenges/>

Transmission scenarios influence the predictive values of SARS-CoV-2 testing - examples

For example, when applying this to Ag-RDTs with 80% sensitivity and 97% specificity

in a fever clinic with a 27% prevalence of COVID-19:

91% of chance that a person testing POSITIVE for COVID-19 truly has COVID-19

at border screening with a 1% prevalence of COVID-19:

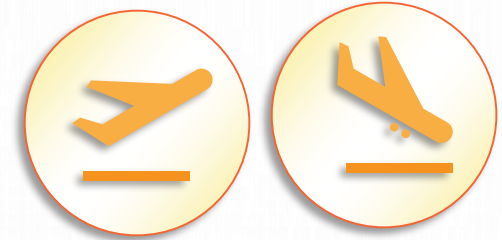
21% of chance that a person testing POSITIVE for COVID-19 truly has COVID-19

→ Therefore, in populations with few or no cases, it is preferable to use the reference NAAT to diagnose cases, as it better correctly identifies persons without COVID-19

<https://www.who.int/publications/i/item/9789240017740>

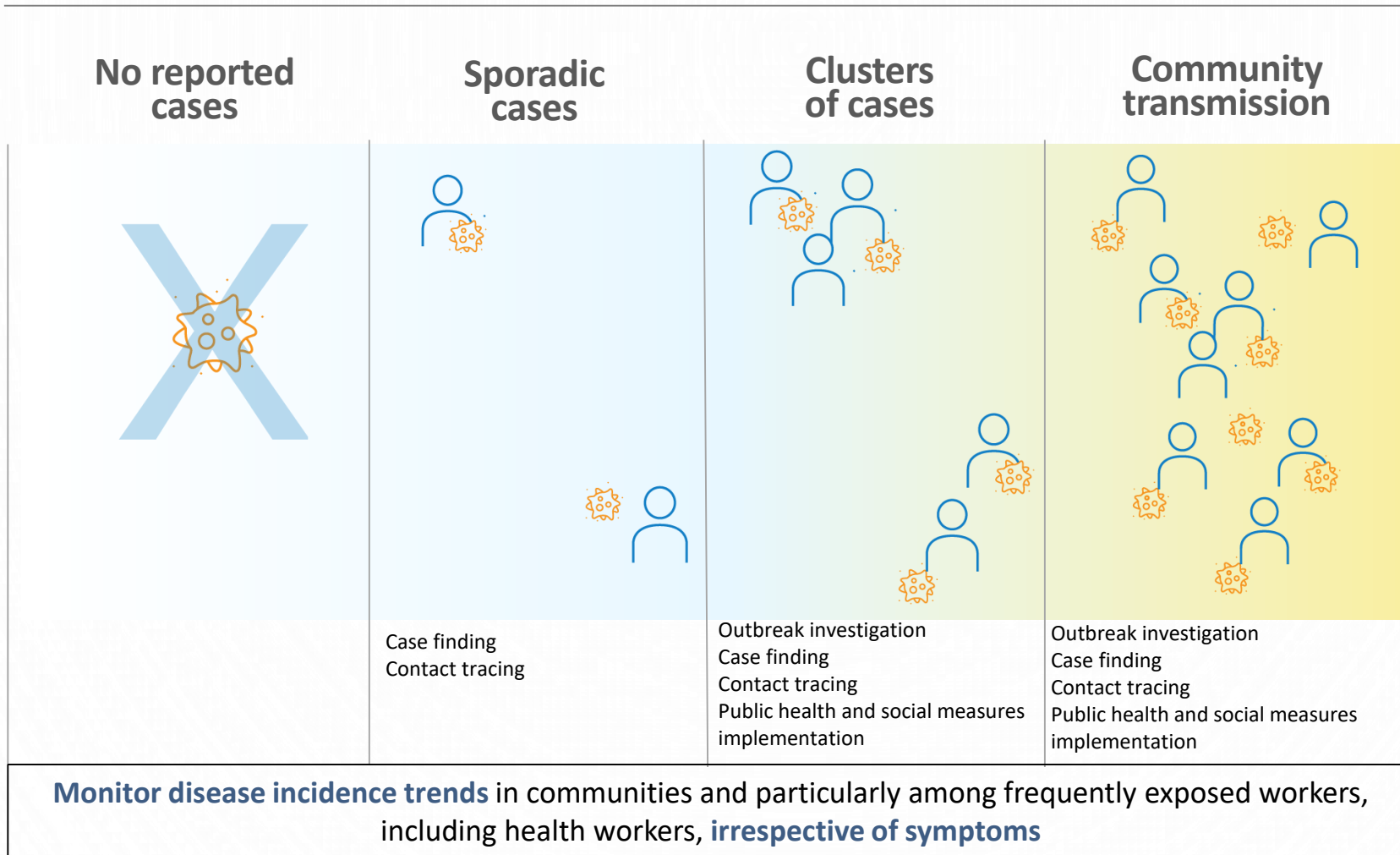
Testing for COVID-19 in the context of international travel

- Many countries test international travelers for SARS-CoV-2 prior to travel, at points of entry or after travel
- The prevalence of SARS-CoV-2 infection among travelers is expected to be low compared to the general population, considering that symptomatic travelers are prevented from travelling. This influences the predictive value of testing
- **WHO does not recommend testing for healthy travelers, particularly where resources may be limited and/or diverted away from priority testing groups.** Countries with sufficient resources that decide to implement testing of travelers, should do so based on risk assessment
- The risk assessment should consider the local epidemiological situation, health system capacities, volume of travel and arrangements for follow-up of incoming travelers who test positive
- **Testing does not replace public health & social measures for epidemic control**
- **Negative results from pre-travel testing cannot guarantee that travelers are free from infection at the time of travel**
- Negative results may generate a false sense of security and disregard the precaution measures during travel and at arrival
- **WHO does not recommend the issuance of so-called ‘immunity passports’**



https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-international_travel_testing-2020.1
https://apps.who.int/iris/bitstream/handle/10665/331866/WHO-2019-nCoV-Sci_Brief-Immunity_passport-2020.1-eng.pdf
<https://apps.who.int/iris/bitstream/handle/10665/331512/WHO-2019-nCoV-POEmgmt-2020.2-eng.pdf>

Limiting SARS-CoV-2 transmission in different scenarios



Resources

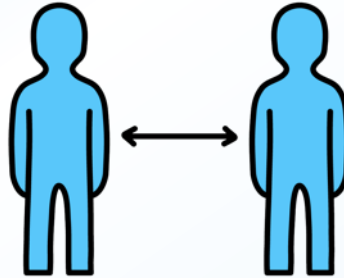
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- <https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2>
- https://www.who.int/docs/default-source/coronaviruse/risk-comms-updates/update-23-epi-win-diagnostics-testing.pdf?sfvrsn=572ed182_2
- <https://www.who.int/publications/i/item/considerations-in-adjusting-public-health-and-social-measures-in-the-context-of-covid-19-interim-guidance>
- https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-international_travel_testing-2020.1
- https://apps.who.int/iris/bitstream/handle/10665/331866/WHO-2019-nCoV-Sci_Brief-Immunity_passport-2020.1-eng.pdf
- <https://www.who.int/publications/i/item/10665-336265>

COVID-19 protection measures

Protect yourself & others



Wear a mask



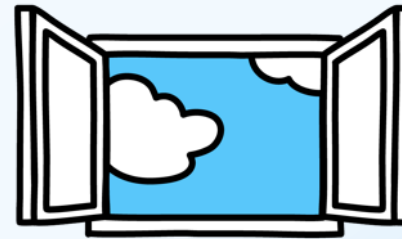
Keep your distance



Wash your hands frequently



Cough & sneeze into your elbow



Ventilate or open windows



EPI•WIN

infodemic
MANAGEMENT

www.who.int/epi-win