https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html

Overview of Testing for SARS-CoV-2

Updated July 17, 2020
Related Pages

Note: This document is intended to provide guidance on the appropriate use of testing and does not dictate the determination of payment decisions or insurance coverage of such testing for people residing in the United States, except as may be otherwise referenced (or prescribed) by another entity or federal or state agency.

Summary of Changes

Revisions made on July 17, 2020

- Except for rare situations, a test-based strategy is no longer recommended to determine when an individual with SARS-CoV-2 infection is no longer infectious (e.g., to discontinue Transmission-Based Precautions or home isolation)

Revisions were made on July 2, 2020, to:

- Added screening to possible testing types
- Removed examples – please refer to setting specific guidance

This document provides a summary of considerations and current Centers for Disease Control and Prevention (CDC) recommendations regarding SARS-CoV-2 testing strategy. The CDC recommendations for SARS-CoV-2 testing have been developed based on what is currently known about COVID-19 and are subject to change as additional information becomes available.

Recommendations for Viral Testing, Specimen Collection, and Reporting

Authorized assays for viral testing include those that detect SARS-CoV-2 nucleic acid or antigen. Viral (nucleic acid or antigen) tests check samples from the respiratory system (such as nasal swabs) and determine whether an infection with SARS-CoV-2, the virus that causes COVID-19, is present. Viral tests are recommended to diagnose acute infection. Some tests are point-of-care tests, meaning results may be available at the testing site in less than an hour. Other tests must be sent to a laboratory to analyze, a process that may take 1-2 days once received by the lab. Testing the same individual more than once in a 24-hour period is not recommended.

For more information on testing for COVID-19 see the Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens and Biosafety FAQs for handling and processing specimens from possible cases.

Recommendations for Antibody Testing

CDC does not currently recommend using antibody testing as the sole basis for diagnosis of acute infection, and antibody tests are not authorized by FDA for such diagnostic purposes. In certain situations, serologic assays may be used to support clinical assessment of persons who present late in their illnesses when used in conjunction with viral detection tests. In addition, if a person is suspected to have post-infectious syndrome

(e.g., Multisystem Inflammatory Syndrome in Children) caused by SARS-CoV-2 infection, serologic assays may be used.

Serologic assays for SARS-CoV-2, now broadly available, can play an important role in understanding the transmission dynamic of the virus in the general population and identifying groups at higher risk for infection. Unlike viral direct detection methods, such as nucleic acid amplification or antigen detection tests that can detect acutely infected persons, antibody tests help determine whether the individual being tested was previously infected—even if that person never showed symptoms.

Categories for SARS-CoV-2 Testing

This document describes five populations for which SARS-CoV-2 testing with viral tests (i.e., nucleic acid or antigen tests) is appropriate:

- Individuals with signs or symptoms consistent with COVID-19
- Asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2 to control transmission
- Asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings
- Individuals being tested to determine resolution of infection (i.e., test-based strategy for Discontinuation of Transmission-based Precautions, HCP Return to Work, and Discontinuation of Home Isolation)
- Individuals being tested for purposes of public health surveillance for SARS-CoV-2

Generally, viral testing for SARS-CoV-2 is considered to be diagnostic when conducted among individuals with symptoms consistent with COVID-19 or among asymptomatic individuals with known or suspected recent exposure to SARS-CoV-2 to control transmission, or to determine resolution of infection. Viral testing is screening when conducted among asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification, and surveillance when conducted among asymptomatic individuals to detect transmission hot spots or characterize disease trends.

Recommended testing for individuals with signs or symptoms consistent with COVID-19

CDC recommends using authorized nucleic acid or antigen detection assaysexternal icon that have received an FDA EUA to test persons **with** symptoms when there is a concern of potential COVID-19. Tests should be used in accordance with the authorized labeling; providers should be familiar with the tests' performance characteristics and limitations.

Clinicians should use their judgment to determine if a patient has signs or symptoms compatible with COVID-19 and whether the patient should be tested. Most patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough) but some infected patients may present with other symptoms (e.g., altered smell or taste) as well. Clinicians are encouraged to consider testing for other causes of respiratory illness, for example influenza, in addition to testing for SARS-CoV-2 depending on patient age, season, or clinical setting; detection of one respiratory pathogen (e.g., influenza) does not exclude the potential for co-infection with SARS-CoV-2. Because symptoms and presentations may be different in children, consider referencing the CDC guidelines for COVID-19 in neonates and for Multisystem Inflammatory Syndrome in Children (MIS-C).

The severity of symptomatic illness due to infection with SARS-CoV-2 may vary from person to person. Among persons with extensive and close contact to vulnerable populations (e.g., healthcare personnel [HCP]),

even mild signs and symptoms (e.g., sore throat) of a possible SARS-CoV-2 infection should prompt consideration for testing. Additional information is available in CDC's Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2.

Recommended testing for asymptomatic individuals with known or suspected exposure to SARS-CoV-2 to control transmission

Testing is recommended for all close contacts of persons with SARS-CoV-2 infection. Because of the potential for asymptomatic and pre-symptomatic transmission, it is important that contacts of individuals with SARS-CoV-2 infection be quickly identified and tested.

- In areas where testing is limited, CDC has established a testing hierarchy; refer to the Interim Guidance on Developing a COVID-19 Case Investigation and Contact Tracing Plan for more information.

In some settings, broader testing, beyond close contacts, is recommended as a part of a strategy to control transmission of SARS-CoV-2. This includes high-risk settings that have potential for rapid and widespread dissemination of SARS-CoV-2 or in which populations at risk for severe disease could become exposed. Expanded testing might include testing of individuals on the same unit or shift as someone with SARS-CoV-2 infection, or even testing all individuals within a shared setting (e.g., facility-wide testing).

Recommended testing for asymptomatic individuals without known or suspected SARS-CoV-2 exposure for early identification in special settings

Certain settings can experience rapid spread of SARS-CoV-2. This is particularly true for settings with vulnerable populations in close quarters for extended periods of time.

Local, territorial, tribal, and state health departments can help with informed decision-making about testing at these or other settings. Before testing large numbers of asymptomatic individuals without known or suspected exposure, facility leadership should have a plan in place for how they will modify operations based on test results.

- Approaches for early identification of asymptomatic individuals include, initial testing of everyone in the setting, periodic (e.g., weekly) testing of everyone in the setting, and testing of new or returning entrants into the setting.

Recommended testing to determine resolution of infection with SARS-CoV-2

A test-based strategy, which requires serial tests and improvement of symptoms, could be considered for discontinuing Transmission-based Precautions or allowing HCP to return to work earlier than the symptom-based strategy. However, in most cases, the test-based strategy results in prolonged isolation of patients or work exclusion of HCP who continue to shed detectable SARS-CoV-2 RNA but are no longer infectious. A test-based strategy could also be considered for some individuals (e.g., those who are severely immunocompromised) in consultation with local infectious diseases experts if concerns exist for the individual being infectious for more than 20 days. In all other circumstances, the symptom-based strategy should be used to determine when to discontinue Transmission-Based Precautions or when HCP can return to work.

This strategy is described in the following documents:

- Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings
- Discontinuation of Isolation for Persons with COVID -19 Not in Healthcare Settings
- Assessing Criteria for Return to Work for Healthcare Personnel with Suspected or Confirmed COVID-19

Public health surveillance for SARS-CoV-2

Testing is a fundamental part of the United States SARS-CoV-2 Surveillance Plan, which uses multiple surveillance systems and epidemiology networks to monitor the progression and impact of SARS-CoV-2 spread in the United States.

Tests are used in community, outpatient, and hospital-based surveillance systems to identify cases of SARS-CoV-2 infection. These data help identify areas of ongoing circulation, determine trends in disease by location, provide insight into the impact of the disease over time and by location, and inform disease forecasts.

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Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases

https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html#severe-illness

https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html

Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings

Interim Guidance

Updated July 20, 2020

CDC guidance for COVID-19 may be adapted by state and local health departments to respond to rapidly changing local circumstances.

Summary Page

Who this is for:

Healthcare providers and public health officials managing persons with coronavirus disease 2019 (COVID-19) under isolation who are not in healthcare settings. This includes, but is not limited to, at home, in a hotel or dormitory room, or in a group isolation facility.

For Hospitalized Patients, see (Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings (Interim Guidance).

Summary of Recent Changes

Updates as of July 20, 2020

- A test-based strategy is no longer recommended to determine when to discontinue home isolation, except in certain circumstances.

- Symptom-based criteria were modified as follows:
  - Changed from "at least 72 hours" to "at least 24 hours" have passed *since last* fever without the use of fever-reducing medications.
  - Changed from "improvement in respiratory symptoms" to "improvement in symptoms" to address expanding list of symptoms associated with COVID-19.

- For patients with severe illness, duration of isolation for up to 20 days after symptom onset may be warranted. Consider consultation with infection control experts.
- For persons who never develop symptoms, isolation and other precautions can be discontinued 10 days after the date of their first positive RT-PCR test for SARS-CoV-2 RNA.

A summary of current evidence and rationale for these changes is described in the Duration of Isolation and Precautions for Adults with COVID-19.

Previous Updates

The CDC is learning more about COVID-19 every day, and as new information becomes available, CDC will update the information below. This guidance is based on available information about COVID-19 and is subject to change as additional information becomes available.

The approach outlined below may differ from that recommended for healthcare personnel or patients in healthcare settings with COVID-19 due to different susceptibilities and risks associated with onward transmission in a healthcare setting.

Other Resources:

- Specific guidance for return to work for healthcare personnel can be found at: Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19.
- Guidance for Discontinuation of Transmission-Based Precautions and Disposition of Patients with SARS-CoV-2 Infection in Healthcare Settings (Interim Guidance) is also available.

Discontinuing Home Isolation for Persons with COVID-19:

Accumulating evidence supports ending isolation and precautions for persons with COVID-19 using a symptom-based strategy. Specifically, researchers have reported that people with mild to moderate COVID-19 remain infectious no longer than 10 days after their symptoms began, and those with more severe illness or those who are severely immunocompromised remain infectious no longer than 20 days after their symptoms began. Therefore, CDC has updated the recommendations for discontinuing home isolation as follows:

Persons with COVID-19 who have symptoms and were directed to care for themselves at home may discontinue isolation under the following conditions:

- At least 10 days* have passed since symptom onset **and**
- At least 24 hours have passed since resolution of fever without the use of fever-reducing medications **and**
- Other symptoms have improved.

*A limited number of persons with severe illness may produce replication-competent virus beyond 10 days, that may warrant extending duration of isolation for up to 20 days after symptom onset. Consider consultation with infection control experts. See Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings (Interim Guidance).

Persons infected with SARS-CoV-2 who never develop COVID-19 symptoms may discontinue isolation and other precautions 10 days after the date of their first positive RT-PCR test for SARS-CoV-2 RNA.

Role of testing for discontinuing isolation or precautions:

RT-PCR testing for detection of SARS-CoV-2 RNA for discontinuing isolation could be considered for persons who are severely immunocompromised[1], in consultation with infectious disease experts. For all others, a test-based strategy is no longer recommended except to discontinue isolation or other precautions earlier than would occur under the symptom-based strategy outlined above.

The test-based strategy requires negative results using RT-PCR for detection of SARS-CoV-2 RNA under an FDA Emergency Use Authorization (EUA) for COVID-19 from at least two consecutive respiratory specimens collected ≥24 hours apart (total of two negative specimens).[†] See Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19).

†All test results should be final before isolation is ended. Testing guidance is based on limited information and is subject to change as more information becomes available.

Other Considerations

Note that recommendations for discontinuing isolation in persons known to be infected with SARS-CoV-2 could, in some circumstances, appear to conflict with recommendations on when to discontinue quarantine for persons known to have been ***exposed*** to SARS-CoV-2. CDC recommends 14 days of quarantine **after exposure** based on the time it takes to develop illness if infected. Thus, it is possible that a person *known* to be infected could leave isolation earlier than a person who is quarantined because of the *possibility* they are infected.

These recommendations will prevent most, but cannot prevent all, instances of secondary spread. The best available evidence suggests that recovered persons can continue to shed detectable SARS-CoV-2 RNA in upper respiratory specimens for up to 3 months after illness onset, albeit at concentrations considerably lower than during illness, in ranges where replication-competent virus has not been reliably recovered and infectiousness is unlikely. Studies have not found evidence that clinically recovered persons with persistence of viral RNA have transmitted SARS-CoV-2 to others.

Footnotes

*All test results should be final before isolation is ended. Testing guidance is based upon limited information and is subject to change as more information becomes available. In persons with a persistent productive cough, SARS-CoV-2-RNA might be detected for longer periods in sputum specimens than in respiratory specimens.

Previous Updates

Updates as of July 17, 2020

- Symptom-based criteria were modified as follows:
    - Changed from "at least 72 hours" to "at least 24 hours" have passed *since last* fever without the use of fever-reducing medications
    - Changed from "improvement in respiratory symptoms" to "improvement in symptoms" to address expanding list of symptoms associated with COVID-19
- A summary of current evidence and rationale for these changes is described in a Decision Memo.

Updates as of May 29, 2020

Added information around the management of persons who may have prolonged viral shedding after recovery.

Updates as of May 3, 2020

- Changed the name of the 'non-test-based strategy' to the 'symptom-based strategy' for those with symptoms. Added a 'time-based strategy' and named the 'test-based strategy' for asymptomatic persons with laboratory-confirmed COVID-19. Extended the home isolation period from 7 to 10 days *since symptoms first appeared* for the symptom-based strategy in persons with COVID-19 who have symptoms and from 7 to 10 days after the date of their first positive test for the time-based strategy in asymptomatic persons with laboratory-confirmed COVID-19. This update was made based on evidence suggesting a longer duration of viral shedding and will be revised as additional evidence becomes available. This time period will capture a greater proportion of contagious patients; however, it will not capture everyone.

- Removed specifying use of nasopharyngeal swab collection for the test-based strategy and linked to the Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for Coronavirus Disease 2019 (COVID-19), so that the most current specimen collection strategies are recommended.

Updates as of April 4, 2020

- Revised title to include isolation in all settings other than health settings, not just home.

Additional Resources

- Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)
- Interim Guidance for Implementing Home Care of People Not Requiring Hospitalization for Coronavirus Disease 2019 (COVID-19)
- Guidance for Healthcare Workers about COVID-19 Testing
- Guidance for Health Departments about COVID-19 Testing in the Community

[1] The studies used to inform this guidance did not clearly define "severely immunocompromised." For the purposes of this guidance, CDC used the following definition:

- Some conditions, such as being on chemotherapy for cancer, untreated HIV infection with CD4 T lymphocyte count < 200, combined primary immunodeficiency disorder, and receipt of prednisone >20mg/day for more than 14 days, may cause a higher degree of immunocompromise and inform decisions regarding the duration of isolation.
- Other factors, such as advanced age, diabetes mellitus, or end-stage renal disease, may pose a much lower degree of immunocompromise and not clearly affect decisions about duration of isolation.
- Ultimately, the degree of immunocompromise for the patient is determined by the treating provider, and preventive actions are tailored to each individual and situation.

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