



# National Notifiable Diseases Surveillance System (NNDSS)

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## Coronavirus Disease 2019 (COVID-19) 2021 Case Definition

**NOTE:** A surveillance case definition is a set of uniform criteria used to define a disease for public health surveillance. Surveillance case definitions enable public health officials to classify and count cases consistently across reporting jurisdictions. Surveillance case definitions are not intended to be used by healthcare providers for making a clinical diagnosis or determining how to meet an individual patient's health needs.

### CSTE Position Statement(s)

21-ID-01

### Background

In late December 2019, investigation of a cluster of pneumonia cases of unknown origin in Wuhan, China, resulted in identification of a novel coronavirus. The virus is distinct from, although closely related to, both severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV). Epidemiologic findings indicate COVID-19 may be less severe<sup>1</sup> than SARS or MERS, but evidence suggests that the virus is more contagious than its predecessors. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a newly identified pathogen, and it is assumed there is no pre-existing human immunity to the virus. There are risk factors that increase an individual's illness severity.

Those at highest risk for severe disease and death include people aged over 60 years (especially those 85 years and older) and those with underlying conditions, including but not limited to obesity, hypertension, diabetes, cardiovascular disease, chronic respiratory or kidney disease, immunosuppression from solid organ transplant, and sickle cell disease. A complete list can be found at: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>. Disease in children mostly appears to be relatively mild, and there is evidence that a significant proportion of infections across all age groups are asymptomatic, or presymptomatic at the time of testing.

Cases of COVID-19 in China and the initial U.S. cases in early March 2020 were clustered. Most cases in China occurred in households, and in Washington, for example, a significant cluster was associated with a long-term care facility. By mid-March, multiple areas in the United States reported cases with no direct epidemiologic link to confirmed cases.

As of March 2021, widespread community transmission of SARS-CoV-2 was documented throughout the United States and globally, and virus variants are circulating widely.

Because of the rapid advancement in the science of COVID-19 disease and SARS-CoV-2 infection, the Council of State and Territorial Epidemiologists (CSTE) is revising position statement 21-ID-01 to update clinical criteria determined to be indicative of infection; refine laboratory criteria to include genomic sequencing; and acknowledge testing performed in non-traditional settings such as work sites, temporary testing sites, at-home tests, and others. Updated criteria for enumerating a case of reinfection are included based on recent studies indicating that different sequenced SARS-CoV-2 strains can be detected at different time points from weeks to months after initial diagnosis.<sup>2</sup>

### Clinical Criteria

#### In the absence of a more likely diagnosis:

- Acute onset or worsening of at least two of the following symptoms or signs:
  - fever (measured or subjective),

- chills,
- rigors,
- myalgia,
- headache,
- sore throat,
- nausea or vomiting,
- diarrhea,
- fatigue,
- congestion or runny nose.

**OR**

- Acute onset or worsening of any one of the following symptoms or signs:
  - cough,
  - shortness of breath,
  - difficulty breathing,
  - olfactory disorder,
  - taste disorder,
  - confusion or change in mental status,
  - persistent pain or pressure in the chest,
  - pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone,
  - inability to wake or stay awake.

**OR**

- Severe respiratory illness with at least one of the following:
  - Clinical or radiographic evidence of pneumonia,
  - Acute respiratory distress syndrome (ARDS).

## Laboratory Criteria

Laboratory evidence using a method approved or authorized by the U.S. Food and Drug Administration (FDA)<sup>3</sup> or designated authority\*:

*Confirmatory\*\* laboratory evidence:*

- Detection of SARS-CoV-2 ribonucleic acid (RNA) in a post-mortem respiratory swab or clinical specimen using a diagnostic molecular amplification test performed by a Clinical Laboratory Improvement Amendments (CLIA)-certified provider, **OR**
- Detection of SARS-CoV-2 by genomic sequencing\*\*\*.

*Presumptive\*\* laboratory evidence:*

- Detection of SARS-CoV-2 specific antigen in a post-mortem obtained respiratory swab or clinical specimen using a diagnostic test performed by a CLIA-certified provider.

*Supportive\*\* laboratory evidence:*

- Detection of antibody in serum, plasma, or whole blood specific to natural infection with SARS-CoV-2 (antibody to nucleocapsid protein), **OR**
- Detection of SARS-CoV-2 specific antigen by immunocytochemistry in an autopsy specimen, **OR**
- Detection of SARS-CoV-2 RNA or specific antigen using a test performed without CLIA oversight.

*\*On March 13, 2020, the President issued a Memorandum on Expanding State-Approved Diagnostic Tests: "Should additional States request flexibility to authorize laboratories within the State to develop and perform tests used to detect COVID-19, the Secretary shall take appropriate action, consistent with law, to facilitate the request."*

*\*\*The terms confirmatory, presumptive, and supportive are categorical labels used here to standardize case classifications for public health surveillance. The terms should not be used to interpret the utility or validity of any laboratory test methodology.*

*\*\*\*Some genomic sequencing tests that have been authorized for emergency use by the FDA do not require an initial polymerase chain reaction (PCR) result to be generated. Genomic sequencing results may be all the public health agency receives.*

## Epidemiologic Linkage

One or more of the following exposures in the prior 14 days:

- Close contact<sup>†</sup> with a confirmed or probable case of COVID-19 disease; **OR**
- Member of an exposed risk cohort as defined by public health authorities during an outbreak or during high community transmission.

<sup>†</sup>Close contact is generally defined as being within 6 feet for at least 15 minutes (cumulative over a 24-hour period). However, it depends on the exposure level and setting; for example, in the setting of an aerosol-generating procedure in healthcare settings without proper personal protective equipment (PPE), this may be defined as any duration.

## Criteria to Distinguish a New Case from an Existing Case

The following should be enumerated as a new case:

- SARS-CoV-2 sequencing results from the new positive specimen and a positive specimen from the most recent previous case demonstrate a different lineage,

**OR**

- Person was most recently enumerated as a confirmed or probable case with onset date (if available) or first positive specimen collection date for that classification >90 days prior<sup>‡</sup>,

**OR**

- Person was previously reported but not enumerated as a confirmed or probable case (i.e., suspect)<sup>##</sup>, but now meets the criteria for a confirmed or probable case.

<sup>‡</sup>Some individuals, e.g., severely immunocompromised persons, can shed SARS-CoV-2 detected by molecular amplification tests >90 days after infection. For severely immunocompromised individuals, clinical judgment should be used to determine if a repeat positive test is likely to result from long-term shedding and, therefore, not be enumerated as a new case. CDC defines severe immunocompromise as certain conditions, such as being on chemotherapy for cancer, untreated human immunodeficiency virus (HIV) infection with CD4 T lymphocyte count <200, combined primary immunodeficiency disorder, and receipt of prednisone >20mg/day for more than 14 days.

<sup>##</sup>Repeat suspect cases should not be enumerated.

## Case Classification

### Suspect

- Meets supportive laboratory evidence<sup>††</sup> with no prior history of being a confirmed or probable case.

<sup>††</sup> *For suspect cases, jurisdictions may opt to place them in a registry for other epidemiological analyses or investigate to determine probable or confirmed status.*

## Probable

- Meets clinical criteria **AND** epidemiologic linkage with no confirmatory or presumptive laboratory evidence for SARS-CoV-2, **OR**
- Meets presumptive laboratory evidence, **OR**
- Meets vital records criteria with no confirmatory laboratory evidence for SARS-CoV-2.

## Confirmed

- Meets confirmatory laboratory evidence.

## Other Criteria

### Vital Records Criteria

A death certificate that lists COVID-19 disease or SARS-CoV-2 or an equivalent term as an underlying cause of death or a significant condition contributing to death.

## References

1. The Novel Coronavirus Pneumonia Emergency Response Epidemiology Team. The Epidemiological Characteristics of an Outbreak of 2019 Novel Coronavirus Diseases (COVID-19) in China. *Zhonghua Liu Xing Bing Xue Za Zhi*. 2020;41(2):145–151. DOI:10.3760/cma.j.issn.0254-6450.2020.02.003.
2. Wang J, Kaperak C, Sato T, Sakuraba A. COVID-19 reinfection: A Rapid Systematic Review of Case Reports and Case Series. *medRxiv*. 2021 <https://jim.bmj.com/content/69/6/1253>.
3. FDA Emergency Use Authorizations <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations> and <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2#nolonger>.

## Related Case Definition(s)

- [Coronavirus Disease 2019 \(COVID-19\) | 2020 Interim Case Definition, Approved April 5, 2020](#)
- [Coronavirus Disease 2019 \(COVID-19\) | 2020 Interim Case Definition, Approved August 5, 2020](#)

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