TEXAS Health and Human Services

Texas Department of State Health Services

COVID-19 Epi Case Criteria Guide

Condition/Code	Case Definition/Case Classification	Laboratory Evidence
Novel Coronavirus 2019 11065	A novel coronavirus is a newly identified coronavirus that has not been previously identified in the human population and it is assumed there is no existing immunity to the virus. The virus (SARS-CoV-2) causing coronavirus disease 2019 (COVID-19), first identified in Wuhan, China in 2019 is not the same as coronaviruses that commonly circulate among humans and cause mild illness, like the common cold. The virus is distinct from although closely related to both SARS-CoV and MERS-CoV. Epidemiologic findings indicate COVID-19 may be less severe than SARS or MERS, but evidence suggests that the virus is more contagious than its predecessors†. SARS-CoV-2 is a newly identified pathogen and it is assumed there was 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-extraprecautions/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. Symptoms of COVID-19 are non-specific and the disease presentation can range from no symptoms (asymptomatic) to severe pneumonia and death. People with COVID-19 generally develop signs and symptoms, including mild respiratory symptoms and fever ~5 days after infection (mean incubation period 5-6 days, range 1-14 days). In accordance with The Council of State and Territorial Epidemiologists (CSTE) Update to the standardized surveillance case definition and national notification for 2019 novel coronavirus disease (COVID-19) Interim-20-ID-02, DSHS has adopted the following case classification strategy effective November 1, 2021; *† 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.*	*Laboratory evidence using a method approved or authorized by the FDA[1] or designated authority[2]: *Confirmatory[3] laboratory evidence*: • Detection of SARS-CoV-2 RNA in a post-mortem respiratory swab or clinical specimen using a diagnostic molecular amplification test performed by a CLIA-certified provider, **OR** • Detection of SARS-CoV-2 by genomic sequencing[4]. *Presumptive[3] 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[3] laboratory evidence:* • Detection of antibody in serum, plasma, or whole blood specific to natural infection with SARSCoV-2 (antibody to nucleocapsid protein), **OR**

Confirmed: A case that meets confirmatory laboratory evidence*

Probable: A case that:

- Meets clinical criteria AND epidemiologic linkage criteria with no confirmatory laboratory testing performed for SARS-CoV-2,

  OR

- Meets presumptive laboratory evidence*

  OR

- Meets vital records criteria (death certificate lists COVID-19 disease or SARS-CoV-2 as an underlying cause of death or a significant condition contributing to death) with no confirmatory laboratory testing performed for SARS-CoV-2.

Suspect: A case that:

- Meets supportive laboratory evidence* with no prior history of being a confirmed or probable case.

Laboratory Criteria for Reporting

- Detection of SARS-CoV-2 RNA in a post-mortem obtained respiratory swab or clinical specimen using a diagnostic molecular amplification test performed by a CLIA-certified provider,

OR

- Detection of SARS-CoV-2 genomic sequence,

OR

- 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

OR

- Detection of SARS-CoV-2 nucleocapsid and spike protein receptor binding domain (RBD) specific antibodies in serum, plasma, or whole blood by a CLIA-certified provider.

NOTE: Testing performed by individuals at home using over-the-counter test kits is considered supportive laboratory evidence due to lack of CLIA oversight.

- 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.

1. FDA Emergency Use Authorizations https://www.fda.gov/medical-devices/emergency-situations-medicaldevices/emergency-use-authorizations and https://www.fda.gov/medical-devices/emergency-situationsmedical-devices/faqs-testing-sars-cov-2#nolonger

2. 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."

3. 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.

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

Clinical Criteria for Reporting:

In the absence of a more likely diagnosis, any medically-attended (including symptoms ascertained telephonically by public health staff, e.g., contact tracers) person with:

- 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).

Epidemiologic Linkage Criteria for Reporting:

A person meeting the clinical reporting criteria with one or more of the following exposures in the 14 days before onset of symptoms:

- Close contact** 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.

***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.*

Vital Records Criteria for Reporting:

A person whose death certificate 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.

Other Criteria for Reporting:

Autopsy findings consistent with pneumonia or acute respiratory distress syndrome without an identifiable cause.

Criteria to distinguish a new case of this disease or condition from reports or notifications which should not be enumerated as a new case for surveillance:

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‡,

OR

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

‡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 HIV infection with CD4 T lymphocyte count 20mg/day for more than 14 days.

‡‡Repeat suspect cases should not be enumerated.