August 10, 2020

COVID-19 Case Classification

Clinical Criteria:

At least <u>two</u> of the following symptoms:

- Fever (subjective or measured)
- Chills
- Rigors
- Myalgia
- Headache
- Sore throat
- Nausea or vomiting,
- Diarrhea
- Fatigue
- Congestion or runny nose

OR

At least <u>one</u> of the following symptoms:

- Cough
- Shortness of breath
- Difficulty breathing
- New olfactory disorder
- New taste disorder

OR

Severe respiratory illness with at least one of the following:

- Clinical or radiologic evidence of pneumonia, or
- Acute respiratory distress syndrome (ARDS)

AND

No alternative more likely diagnosis

Laboratory Criteria:
Method used as laboratory evidence should be approved or authorized by the FDA*

Confirmatory laboratory evidence:
- Detection of SARS-CoV-2 RNA in a clinical or autopsy specimen using a molecular amplification test (various nomenclature: NAT, NAA, NAAT, PCR, RNA, RT-PCR, r RT-PCR, etc.)

Presumptive** laboratory evidence:
- Detection of SARS-CoV-2 by antigen test in a respiratory specimen

Supportive** laboratory evidence:
- Detection of specific antibody to SARS-CoV-2 (IgM, IgG, or total [IgM + IgG]) in serum, plasma, or whole blood
- Detection of specific SARS-CoV-2 antigen by immunocytochemistry in an autopsy specimen

* For a current list of SARS-CoV-2 EUA tests please see: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

**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.

Epidemiological Evidence:
One or more of the following exposures in the last 14 days before onset of symptoms or positive test:
- Close contact* with a confirmed or probable case of COVID-19 disease; or
- Member of a risk cohort** as defined by public health authorities during an outbreak

*Close contact is defined as being within 6 feet for at least 15 minutes, and close personal activities, such as hugging or kissing. In healthcare settings, this may be defined as any exposure of greater than a few minutes.

**Examples of a "risk cohort" might be health care workers treating patients with certain respiratory illnesses, staff and residents in long-term care facilities and other confined population environments (behavioral health hospitals, prisons, etc.) with confirmed cases, travel to a defined geographic location with known COVID-19 outbreaks/clusters, or exposure to defined outbreaks/clusters, including business, child care, church, sports team, and other settings.

Vital Records Criteria:
A death certificate that lists COVID-19 disease or SARS-CoV-2 as a cause of death or a significant condition contributing to death (Note: If the cause of death is clearly unrelated to COVID-19, this will not qualify despite laboratory evidence of SARS-CoV-2 infection at time of death).

Case Classification:

Confirmed
- Meets confirmatory laboratory evidence

Probable
- Meets clinical criteria AND epidemiologic evidence with no confirmatory laboratory testing performed for COVID-19 **OR**
- Meets presumptive laboratory evidence **OR**
- Meets supportive laboratory evidence AND either clinical criteria or epidemiologic evidence **OR**
- Meets vital records criteria with no confirmatory laboratory testing performed for COVID-19 unless additional epidemiologic or clinical evidence exists to refute the vital records criteria

Suspect
- Meets supportive laboratory evidence with no prior history of being a confirmed or probable case
- Meets clinical criteria and is epi-linked to a confirmed case, but with one negative confirmatory laboratory test result within two days prior to, or 7 days after symptom onset.*

* Cases with more than one negative confirmatory laboratory test result would not be considered a Suspect case