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Health and Human Services

Texas Department of State
Health Services

COVID-19 Epidemiology Training

Emerging and Acute Infectious Disease Unit

Laboratory & Infectious Disease Services Division

COVID-19 Background

- A cluster of atypical pneumonia that would later be identified as coronavirus disease 2019 (COVID-19), was first reported in Wuhan, China in December 2019. The virus causing COVID-19, SARS-CoV-2, was rapidly identified and the sequence made available online.
- In early March 2020 -Cases of COVID-19 in China and the initial U.S. cases were clustered.
- By mid-March 2020- multiple areas in the U.S. reported cases with no direct epidemiologic link to confirmed cases.
- As of August 2021- widespread community transmission of SARS-CoV-2 has been documented in Texas and throughout the U.S. and virus variants are circulating widely.

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COVID-19 Background

- 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). More serious illness requiring hospitalization or resulting in fatality can occur. There are risk factors including age and certain medical conditions can increase an individual's risk of more severe illness.

- 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 pre-symptomatic at the time of testing.

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COVID-19 Background

- COVID-19 transmission primarily occurs through contact with respiratory fluids carrying virus, through inhalation, direct contact or indirect contact. Transmission by individuals who are asymptomatic or pre-symptomatic has been documented and is thought to contribute to community transmission of SARS-CoV-2.

- August 2021 -more than 2.8 million COVID-19 cases and more than 55,000 COVID-19 associated fatalities reported in Texas.

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COVID-19 Case Classifications

Effective November 1, 2021

Confirmed:

- Meets confirmatory laboratory evidence.

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.

Suspect:

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

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COVID-19 Laboratory Criteria

Laboratory evidence using a method approved or authorized by the FDA or designated authority:

Confirmatory 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.

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 SARSCoV-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.

COVID-19 Laboratory Criteria for Self-Testing Kits

Updates to laboratory evidence clarifies that CLIA status of the setting where the test was **performed**, rather than where the sample was taken, determines the designation of supportive vs probable vs confirmatory laboratory evidence.

This impacts "at home tests" which come in a variety of combinations of setting of sample collection and test processing setting.

For example:

a. At home antigen tests, such as Abbott Binax now antigen tests that are collected and performed **without** CLIA oversite would be considered ***supportive laboratory evidence*** and classified as a **suspect case** if the results were reported to public health.

b. The same test, when administered in another setting **with CLIA certification or waiver and oversight of a provider** (such as in the school testing program run by TDEM, or the antigen testing program administered in TDCJ facilities, or in a nursing home would be considered ***presumptive laboratory evidence*** and the case classified as a **probable case** if there was a positive result. These settings are required to report results to public health.

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COVID-19 Laboratory Criteria for Self-Testing Kits Continued

c. A nucleic acid amplification test (NAAT) performed in a facility **without CLIA certification**, such as the Cue at home NAAT which is a NAAT performed at home and has an FDA EUA would be considered ***supportive laboratory evidence*** and therefore alone a positive test would be classified as a **suspect case** rather than a confirmed case because of the setting where the test was performed.

d. An "At home" collection test, such as a PCR or antigen test where the collection was performed at home, but the **sample was then mailed to a CLIA certified lab** for testing would fall under ***presumptive or confirmatory laboratory evidence***, leading to a positive test under those circumstances being designated as a **probable or confirmed case** based on the test type.

- Of note, if requirements for higher level case classification were obtained later, such as a follow up test performed in a CLIA certified setting, or interview by a public health worker identifying known epidemiologic linkage and symptoms that meet clinical criteria, a suspect case could be upgraded to a probable case in the public health information collection system (i.e. NEDSS).

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COVD-19 Clinical Criteria

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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).

COVID-19 Case Definition Continued

Epidemiologic Linkage

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

- 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.

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.

Other Criteria for Reporting

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

Contact Info

Health and Human Services
Texas Department of State Health Services

For questions or concerns regarding COVID-19, please contact:
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