Coronavirus Disease 2019 (COVID-19) Rev January 2023

BASIC EPIDEMIOLOGY

Infectious Agent

Coronavirus disease 2019 (COVID-19) is caused by the virus severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a new virus in humans causing respiratory illness which can be spread from person-to-person. SARS- CoV-2 is considered a novel coronavirus. The first case of the disease that would later be named COVID-19 was identified in Wuhan, China in December 2019.

Transmission

COVID-19 is primarily transmitted from person-to-person by exposure to infectious respiratory fluids through three primary mechanisms: 1) inhalation of very fine respiratory droplets and aerosol particles, 2) deposition of respiratory droplets and particles on exposed mucous membranes such as in the mouth, nose, or eye by direct splashes and sprays, and 3) by touching mucous membranes with hands that have been soiled either directly by virus containing respiratory fluids, or indirectly by touching surfaces with SARS-CoV-2 virus on them.

Virus containing droplets and particles are released when someone with COVID-19 sneezes, coughs, or talks. Infectious droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs. Respiratory droplets can land on hands, objects or surfaces around the person when they cough or talk, and people can then become infected with COVID-19 from touching hands, objects or surfaces with droplets and then touching their eyes, nose, or mouth. Recent data suggest that there can be transmission of COVID-19 through droplets of those with mild symptoms or those who do not feel ill (transmission by individuals who are asymptomatic or pre-symptomatic). Current data do not support long range aerosol transmission of SARS-CoV-2, such as seen with measles or tuberculosis. Current evidence is supportive of COVID-19 transmission through short-range inhalation of aerosols, similar to many other respiratory pathogens. Short-range transmission is a possibility particularly in crowded medical wards and inadequately ventilated spaces. Certain procedures in health facilities can generate fine aerosols that increase the risk of transmission of SARS-CoV-2 and should be avoided whenever possible.

The risk of SARS-CoV-2 infection increases with the amount of virus to which a person is exposed. Factors that may increase the risk of SARS-CoV-2 transmission can include:

- Enclosed spaces with inadequate ventilation or air handling within which the concentration of exhaled respiratory fluids, especially very fine droplets and aerosol particles, can build-up in the air space.
- **Increased exhalation** of respiratory fluids if the infectious person is engaged in physical exertion or raises their voice (e.g., exercising, shouting, singing).
- **Prolonged exposure** to these conditions, typically more than 15 minutes.

A range of body fluids have been shown to contain SARS-CoV-2 RNA and viable SARS-CoV-2 virus, indicating that they may also be infectious. SARS-CoV-2 viral RNA has been detected in upper and lower respiratory tract specimens and has been isolated from upper respiratory tract specimens and bronchoalveolar lavage fluid. SARS-CoV-2 RNA has been detected in blood and stool specimens, and SARS-CoV-2 virus has been isolated in cell culture from the stool of some patients. The duration of SARS-CoV-2 RNA detection in upper and lower respiratory tract specimens and in extrapulmonary specimens may range from several days to several weeks or longer. Duration of RNA detection several weeks to several months or longer has been observed in cases of acute SARS-CoV-2 infection. See CDC Science Brief: SARS-CoV-2 Transmission for more information: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html

Prevention of Transmission

The infectious dose of SARS-CoV-2 needed to transmit infection has not been established. Current evidence strongly suggests transmission from contaminated surfaces does not contribute substantially to new infections. The relative contributions of inhalation of virus and deposition of virus on mucous membranes remain unquantified and will be difficult to establish. Despite these knowledge gaps, the available evidence continues to demonstrate that existing recommendations to prevent SARS-CoV-2 transmission remain effective. These include physical distancing, community use of well-fitting masks (e.g., barrier face coverings, procedure/surgical masks), adequate ventilation, and avoidance of crowded indoor spaces. These methods will reduce transmission both from inhalation of virus and deposition of virus on exposed mucous membranes. Transmission through soiled hands and surfaces can be prevented by practicing good hand hygiene and by environmental cleaning.

See CDC Science Brief: SARS-CoV-2 Transmission for more information: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html

Incubation Period

The incubation period for SARS-CoV-2 is estimated to range from 2 to 14 days with a median of 3 to 5 days. One study reported that 97.5% of people with COVID-19 who have symptoms will do so within 11.5 days of SARS-CoV-2 infection.

Communicability

The period of communicability for SARS-CoV-2 is not completely understood. Asymptomatic and presymptomatic transmission of SARS-CoV-2 has been documented and there are studies reporting that a significant proportion of COVID-19 transmission occurs while infectious individuals are in their incubation period.

Some studies have suggested transmission as early as five days before symptom onset. There is evidence of the presence of COVID-19 RNA in patient samples for as long as several weeks after symptom onset. However, RNA detection by itself does not necessarily indicate the presence of live virus. Generally, the greatest risk of transmission occurs between 2 days prior to symptom onset to between 3-5 days after symptom onset.

Clinical Illness

Typical symptoms of SARS-CoV-2 include fever or chills, cough, shortness of breath or difficulty breathing, fatigue, headache, nasal congestion or runny nose, muscle or body aches, sore throat, new loss of smell or taste, nausea or vomiting, and diarrhea. The most commonly reported symptoms may differ with severity of disease, presence of underlying conditions or immunosuppression, and may vary by SARS-CoV-2 lineage. For example, shortness of breath is more commonly reported among hospitalized COVID-19 cases than among those who have a milder illness. Older adults and people with underlying comorbidities may experience fever or respiratory symptoms later during the course of infection than those who are younger or do not have comorbidities.

The severity of illness can range from mild or moderate (mild symptoms up to mild pneumonia), severe (dyspnea, hypoxia or more than 50% lung involvement on imaging), to critical (respiratory failure, shock or multiorgan system dysfunction) and depends on a variety of factors, including but not limited to age, underlying medical comorbidities, vaccination status, treatment, and SARS-CoV-2 lineage. Age is a strong risk factor for severe illness, complications, and death due to COVID-19.

Hospitalization may be required for management of severe COVID-19 and the most common complications, which can include pneumonia, hypoxemic respiratory failure/ARDS, sepsis and septic shock, cardiomyopathy, arrhythmia, acute kidney injury, and complications from prolonged hospitalization such as secondary bacterial and fungal infections, thromboembolism, gastrointestinal bleeding and polyneuropathy/myopathy. Strokes, clotting of intra-vascular catheters, and myocardial injury with ST-segment elevation have also been reported due to COVID-19-associated coagulopathy.

A large cohort study that included more than 44,000 people from China conducted in 2020 (Wu and McGoonan,

2020) reported that 81% of cases identified resulted in mild to moderate illness, 14% of cases identified resulted in severe illness, and 5% resulted in critical illness. Other studies reported lower illness severity in children than adults with 94% of children having asymptomatic, mild or moderate disease, 5% having severe disease and less than 1% having critical disease (Dong, Mo, Hu et al., 2020). However, children of all ages with certain underlying medical conditions and infants <12 months of age may be at increased risk of severe illness from COVID-19. Texas DSHS and CDC are also investigating multisystem inflammatory syndrome in children (MIS-C) and multisystem inflammatory syndrome in adults (MIS-A) associated with COVID-19 which is distinct from severe COVID-19 illness in infants and children. See CDC clinical guidance for more details and updated information: www.cdc.gov/coronavirus and www.cdc.gov/coronavirus and www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care.html.

DEFINITIONS

Case definitions for novel coronaviruses evolve as clinical and epidemiologic information on these viruses is updated. Please refer to the COVID-19 novel coronavirus information on DSHS's website for the most recent definitions. The DSHS COVID-19 case definitions may be found here: https://dshs.texas.gov/coronavirus/public-health.aspx

Laboratory Criteria for Reporting

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

OR

Detection of SARS-CoV-2 genomic sequences,

OR

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

*Includes those tests performed under a CLIA certificate of waiver

NOTE: Testing performed by individuals at home using over-the-counter test kits is considered supportive laboratory evidence and should not be included in case counts due to lack of CLIA oversight.

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.

Clinical Criteria for Reporting

N/A

Epidemiologic Linkage Criteria for Reporting

N/A

Other Criteria for Reporting

N/A

Laboratory Evidence

Laboratory evidence using a method approved or authorized by the U.S. Food and Drug Administration (FDA¹) or designated authority²:

Confirmatory** laboratory evidence:

Detection of SARS-CoV-2 RNA in a clinical or post-mortem specimen using a diagnostic molecular EAIDG 2023

amplification test performed by a CLIA-certified provider***,

OR

Detection of SARS-CoV-2 in a clinical or post-mortem specimen by genomic sequencing****.

Presumptive** laboratory evidence:

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

Supportive** Laboratory evidence:

Detection of SARS-CoV-2 specific antigen by immunocytochemistry

OR

Detection of SARS-CoV-2 RNA or specific antigen using a test performed without CLIA oversight.

Footnotes:

- 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."
- **. 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.
- *** Includes those tests performed under a CLIA certificate of waiver.
- **** 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.

Case Classifications

Confirmed: A case that meets confirmatory laboratory evidence*

Probable: A case that meets presumptive laboratory evidence*

Suspect: A case that:

Meets supportive laboratory evidence*

OR

Meets vital records criteria with no confirmatory or presumptive laboratory evidence for SARS-CoV-2

*Includes those tests performed under a CLIA certificate of waiver

NOTE: Testing performed by individuals at home using over-the-counter test kits is considered supportive laboratory evidence and should not be included in case counts due to lack of CLIA oversight

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:

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

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 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.

SURVEILLANCE AND CASE INVESTIGATION

Case Investigation

Local and regional health departments should investigate laboratory, clinical reports and self-reports of SARS-CoV-2 based on the prioritization of case investigations outlined in <u>DSHS Surveillance Case Definitions for Coronavirus Disease 2019 (COVID-19)</u>. The current investigation form for 2019 Novel Coronavirus available at <u>www.dshs.texas.gov/sites/default/files/coronavirus/docs/DSHS-COVID19CaseReportForm.pdf</u>. Completion of a more detailed investigation form may be required for probable or confirmed cases or in the event of an outbreak or other special situation. This more detailed investigation form will be provided by DSHS or may be available at www.dshs.texas.gov/covid-19-coronavirus-disease-2019/information-public-health if needed.

Case Investigation Checklist

- □ Any reported novel coronavirus case should be investigated within 7 days of notifications to the health department if possible. Otherwise, case investigations should be prioritized based on the order outlined in DSHS Surveillance Case Definitions for Coronavirus Disease 2019 (COVID-19).
- ☐ Ensure that appropriate control measures have been implemented (see Prevention and Control Measures, below).
- □ Determine whether the patient meets the case definition.
 - o If needed obtain medical records, interview the suspected case-patient or surrogate and interview the patient's healthcare provider.
- □ Notify DSHS within 7 days of cases of novel coronavirus. Please note laboratory reporting remains subject to GA-38 as long as it remains in effect. See https://www.dshs.texas.gov/covid-19-coronavirus-disease-2019/information-laboratories/complying-governors-order-to for more details.
- □ For any patient who meets case criteria as a probable or confirmed COVID-19 case, complete a case investigation in NBS. Please refer to the *Data Entry Guidelines (DEG)* for specific data entry requirements.

Confirmed/Probable Case Investigation Checklist

Any confirmed or probable COVID-19 cases should be investigated and entered into NEDSS

following case investigation prioritization guidelines, (www.dshs.texas.gov/sites/default/files/coronavirus/docs/DSHS-

COVID19CaseDefinitionandInvestigationPrioritizationGuidance.pdf).

- ☐ Ensure that appropriate control measures have been implemented (see Prevention and Control Measures, below).
- □ Confirm that laboratory results (if available) meet the case definition.
- □ Notify DSHS within 7 days of probable or confirmed cases of coronavirus disease 2019.
- □ Confirmed and probable case investigations must be entered into the COVID-19 program area module (PAM) in the NEDSS Base System (NBS) or complete and return the Coronavirus Disease 2019 (COVID-19) Case Report form. Data sources may include medical records and by interviewing the case-patient or surrogate to identify close contacts, risk factors, and other pertinent information.
 - Completion of a more detailed investigation may be required and will be provided by DSHS, if needed for cases involving reinfection, vaccine breakthrough, or a SARS-CoV-2 variant of concern or variant of high consequence.
- □ Be prepared to enhance surveillance in the local area for respiratory illnesses and respiratory viruses, if requested by DSHS.
 - Refer to the Public Health Preparedness, Surveillance, and Response Plan for Texas:
 Respiratory Viruses Having Pandemic Potential for a list of responsibilities by department and program area, and for action triggers.
- □ If applicable, complete the steps in the Managing Special Situations section.

Prevention and Control Measures

Staying up to date with COVID-19 vaccines significantly lowers the risk of getting very sick, being hospitalized, or dying from COVID-19. DSHS recommends COVID-19 vaccination for everyone included in the current <u>Food and Drug Administration (FDA) emergency use authorizations and approvals</u>. People who are <u>moderately or severely immunocompromised</u> have specific recommendations for COVID-19 vaccines, including boosters.

Please see https://www.dshs.texas.gov/covid-19-coronavirus-disease-2019/covid-19-vaccine-information for updates to COVID-19 vaccine related guidance.

Prevention and control guidelines for SARS-Cov-2 are subject to change as disease knowledge evolves. Please refer to the CDC websites provided below for the most recent updates and recommendations. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html

Additional setting specific guidance may be found at: https://www.dshs.texas.gov/covid-19-coronavirus-disease-2019/information-communities-other-specific-groups

General Population

CDC advises that people follow prevention steps to help reduce their risk of getting infected with respiratory viruses, like SARS-CoV-2:

- Staying Up to Date with COVID-19 Vaccines
- o Improving Ventilation
- Getting Tested for COVID-19 If Needed
- o Following Recommendations for What to Do If You Have Been Exposed
- Staving Home If You Have Suspected or Confirmed COVID-19
- o Seeking Treatment If You Have COVID-19 and Are at High Risk of Getting Very Sick
- o Avoiding Contact with People Who Have Suspected or Confirmed COVID-19
- For more information on COVID-19 vaccination please see https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html.

COVID-19 Prevention

The following prevention steps are recommended for people confirmed to have SARS-CoV-2 infection who can receive care at home and do not need to be hospitalized for medical reasons; people being evaluated by a healthcare provider for SARS-CoV-2 infection; caregivers and household members of a person confirmed to

have, or being evaluated for, SARS-CoV-2 infection; and other people who have had close contact with a person confirmed to have, or being evaluated for, SARS- CoV-2 infection:

Note: If you are confirmed to have, or being evaluated for, SARS-CoV-2 infection you should follow the prevention steps below in accordance with If You Are Sick or Caring for Someone | CDC and How to Protect Yourself and Others | CDC.

- Stay home
 - You should restrict activities outside your home, except for getting medical care. Do not go to work, school, or public areas, and do not use public transportation or taxis.
- Separate yourself from other people in your home
 - As much as possible, you should stay in a different room from other people in your home. Also, you should use a separate bathroom, if available.
- Improve ventilation (air flow) at home to help prevent COVID-19 from spreading to other people
- Wear a high quality facemask or respirator around others
 - You should wear a facemask covering your mouth and nose when you are in the same room with other people and when you visit a healthcare provider. If you cannot wear a facemask, the people who live with you should wear one while they are in the same room with you.
- Practice every day hygiene and cleaning and avoid sharing personal household items
 - Wash hands often
 - Cover coughs and sneezes
- Monitor your symptoms and follow healthcare provider instructions
 - Seek prompt medical attention if your illness is worsening (e.g., difficulty breathing). <u>Before</u> going to your medical appointment, call the healthcare provider and tell him or her that you have, or are being evaluated for, COVID-19 infection. This will help the healthcare provider's office take steps to keep other people from getting infected.

Because updates to isolation guidance is rapidly evolving, please see the <u>Coronavirus Disease 2019</u> <u>homepage on the Texas DSHS website</u> and <u>How to Protect Yourself and Others | CDC</u> for updates for the general public. This does not apply to public school or congregate settings. Please see <u>COVID-19 School Readmission Criteria</u> and <u>DSHS School Health Recommendations for the Prevention and Control of Communicable Diseases in a Group- Care Setting</u> for the most up to date guidance for public school and congregate settings.

Caregivers and Household Members

See Caring for Someone Sick at Home Guidance from CDC for the most updated recommendations.

Travelers and Airline Crew

• Recommendations for travel due to the COVID-19 pandemic are updated frequently, for the latest information refer to the CDC COVID-19 Travel page.

Treatment

Available therapeutics reduce the risk of hospitalization and severe outcomes due to COVID-19 for certain high-risk groups. DSHS recommends the available, oral medication Paxlovid as the first-line treatment for high-risk Texans with symptomatic COVID-19. To find medication, patients should reach out to their healthcare provider or use the Test-to-Treat Locator:

HHS COVID-19 Test-to-Treat Locator

Texans seeking infusion treatments should consider the preferred Paxlovid treatment and talk to a doctor with questions. Please see https://www.dshs.texas.gov/covid-19-coronavirus-disease-2019/covid-19-therapeutics-information for updates and additional information.

Exclusion

Coronavirus disease 2019 commonly referred to as COVID-19 is a disease requiring exclusion from school

under 25 Tex. Admin. Code § 97.7.

A school administrator shall exclude from attendance any child having or suspected of having COVID-19. Exclusion shall continue until the readmission criteria for the conditions are met. The readmission criteria for COVID-19 is as follows:

- If symptomatic, exclude until at least 5 days have passed since symptom onset, and fever free*, and other symptoms have improved.
- Children who test positive for COVID-19 but do not have any symptoms must stay home until at least 5 days after the day they were tested.

*Fever free for 24 hours without the use of fever suppressing medications. Fever is a temperature of 100° Fahrenheit (37.8° Celsius) or higher. Please see <u>COVID-19 School Readmission Criteria</u> and <u>DSHS School Health Recommendations for the Prevention and Control of Communicable Diseases in a Group- Care Setting for the most up to date guidance for public school and congregate settings.</u>

MANAGING SPECIAL SITUATIONS

MIS-C

Multisystem Inflammatory Syndrome in Children (MIS-C) is "Multisystem inflammatory syndrome in children" is an unusual expression of COVID-19 of

public health concern and should be reported to Texas Department of State Health Services. MIS-C is a condition where different body parts can become inflamed. See the DSHS MIS-C webpage for more information: www.dshs.texas.gov/covid-19-coronavirus-disease-2019/texas-covid-19-data/cases-multisystem-inflammatory-syndrome-children

- If a healthcare practitioner reports a suspected MIS-C case to the local health department, the local health department should assess the case and determine if the reported case meets the CDC MIS-C case definition. LHDs should request demographics, history and physical, labs, echo or radiology results if performed, and discharge summary (if available) from the provider to make their assessment.
- Case definition for MIS-C is available at: https://www.cdc.gov/mis/mis-c/hcp_cstecdc/index.html
- If case meets criteria, the local department should:
 - Complete their investigation and enter case into the MIS-C data mart in NEDSS. The LHD should then submit the medical records and case report form (available on the DSHS website) to EAIDU via secure email to EAIDU via secure email to EAIDU without entering the case into NEDSS; EAIDU will enter the case into NEDSS after their review if not already entered.
- For more information on evaluating and reporting cases of MIS-C, please see the <u>Multisystem Inflammatory Syndrome in Children (MIS-C) Reporting Process</u> available on the DSHS website.

SARS-CoV-2 Variants

Viruses like SARS-CoV-2 continuously evolve as changes in the genetic code (genetic mutations) occur during replication of the genome. A lineage is a genetically closely related group of virus variants derived from a common ancestor. A variant has one or more mutations that differentiate it from other variants of the SARS-CoV-2 viruses. Genetic variants of SARS-CoV-2 are circulating locally and globally and are being studied to inform local outbreak investigations and understand differences in transmission and severity of COVID-19 among those infected. DSHS is collecting information about COVID-19 variants of high consequence (VOHC) and variants of concern (VOC) as designated by the CDC. This list may be updated as additional VOHC/VOC are identified. Please see the DSHS Coronavirus Disease 2019 (COVID-19) SARS-CoV-2 Variant Case Guidance on the DSHS website for the most up to date information.

Samples from suspected variant of concern cases and close contacts may be submitted to the DSHS
 Austin Public Health Laboratory for whole genome sequencing. Please see <u>DSHS COVID-19 Next</u>
 Generation Sequencing (NGS) Specimen Collection and Submission Instructions for more

information.

• For more information on investigating or reporting variants, please see the <u>DSHS Coronavirus</u> <u>Disease 2019 (COVID-19) Variant Case Guidance</u> available on the DSHS website.

Reinfection

COVID reinfections should be enumerated as a new case for surveillance purposes.

Guidance is evolving rapidly, for more information or the most up to date guidance about reporting COVID-19 reinfection cases, and the case definition please see the DSHS Coronavirus Disease 2019 (COVID-19) Reinfection Guidance available on the DSHS website at www.dshs.texas.gov/sites/default/files/coronavirus/docs/DSHS-COVID19ReinfectionGuidance.pdf.

Vaccine Breakthrough Cases

Because updates to vaccination guidance is rapidly evolving, please see the Vaccine Breakthrough Guidance available on the DSHS website at https://www.dshs.texas.gov/covid-19-coronavirus-disease-2019/information-public-health for the most up to date information.

Clusters of Patients with Severe Acute Respiratory Illness/Outbreaks of COVID-19

If an outbreak is suspected or there is a cluster of COVID-19 in a jurisdiction, local area or facility, notify EAIDU by submitting a Respiratory Disease Outbreak Summary Form to EAIDU-coronavirus@dshs.texas.gov or by fax to (512) 776-7676.

The local/regional health department should:

- Investigate common exposures among the cases and work with any identified facilities or entities.
 - o Recommend appropriate control measures for the specific entity or setting.
- Monitor individuals exposed to confirmed/probable cases.
 - Collect specimens from individuals exposed to confirmed or probable cases, if requested.
- Encourage persons with compatible symptoms to be evaluated by a healthcare provider.

If appropriate, alert healthcare providers in the area to be cognizant of possible cases and encourage immediate reporting of suspected cases.

REPORTING AND DATA ENTRY REQUIREMENTS

Provider, School, Child-Care Facility, and General Public Reporting Requirements Confirmed and probable cases of SARS-CoV-2 infection are required to be reported to the local or regional health department or the Texas Department of State Health Services (DSHS), Emerging and Acute Infectious Disease Unit (EAIDU) at EAIDU-coronavirus@dshs.texas.gov or by fax to (512) 776-7676.

Local and Regional Reporting and Follow-up Responsibilities

Local and regional health departments should:

- Enter the case into NEDSS and submit an NBS notification on all confirmed and probable cases to DSHS within 7 days of receiving a report of such a case. NBS notifications will be automatically submitted for cases created through the workflow decision support system (WDS) but should be manually submitted for cases that are manually entered.
 - Suspect cases should not be entered into NBS. Please refer to the DSHS NBS Data Entry Guide on the website at www.dshs.texas.gov/sites/default/files/coronavirus/docs/DSHS-COVID19DataEntryGuide.pdf.
 - A notification can be sent as soon as the case criteria have been met. Additional information from the investigation may be entered upon completing the investigation.
- When an outbreak is investigated, local and regional health departments should:
 - o Report outbreaks immediately to the regional DSHS office and or to DSHS EAIDU by secure email to EAIDU-coronavirus@dshs.texas.gov or fax to 512-776-7676.
 - Enter outbreak associated cases into NEDSS and submit an NBS notification on all confirmed and probable cases to DSHS within 7 days. Ensure Outbreak fields outlined in COVID-19 section of DEG are completed and outbreak name entered matches outbreak name included

- on Respiratory Disease Outbreak Summary Form. Addition of outbreak names to NEDSS may be requested using the <u>NEDSS Helpdesk webform</u>
- Submit a completed Respiratory Disease Outbreak Summary Form at the conclusion of the outbreak investigation.
 - Fax or send by secure email a copy to the DSHS regional office and to EAIDU as a secure email to <u>EAIDU-Coronavirus@dshs.texas.gov</u> (fax: 512-776-7676).
- The Respiratory Disease Outbreak Summary Form is available at http://www.dshs.texas.gov/idcu/investigation/.

LABORATORY PROCEDURES

Identification of a novel coronavirus such as SARS-CoV-2 is available in Texas through the DSHS Austin Laboratory, Texas Laboratory Response Network (LRN) laboratories, and commercial laboratories throughout the state can test for SARS-CoV-2. For a list of laboratories in Texas currently qualified to perform novel coronavirus testing, please contact DSHS EAIDU by email at EAIDU-coronavirus@dshs.texas.gov or by fax at 512-776- 7676. Whole genome sequencing is also available at the DSHS Austin Laboratory for certain SARS CoV-2 specimens with epidemiologist approval or that meet priority sequencing criteria and for surveillance samples approved for whole genome sequencing by EAIDU (see

https://www.dshs.texas.gov/sites/default/files/lab/forms/COVID-19-NGS-specimen-collection-and-submission-instructions.pdf for updated information).

Specimen Collection

Please see https://www.dshs.texas.gov/laboratory-services/laboratory-testing-services-manual-guidelines-specimen-collection-submission for the most up-to-date guidelines.

Specimen Type and Priority

Points to consider when determining which specimen types to collect from a patient under investigation for SARS-CoV-2 include:

- The number of days between specimen collection and symptom onset
- Symptoms at the time of specimen collection.

Additional points to consider:

- Maintain proper infection control when collecting specimens
- Use approved collection methods and equipment when collecting specimens
- Handle, store, and ship specimens following appropriate protocols

General Guidelines

For short periods (≤ 72 hours), most specimens should be held at 2-8°C rather than frozen. For delays exceeding 72 hours, freeze specimens at -70°C as soon as possible after collection (with exceptions noted below). Label each specimen container with the patient's ID number, specimen type and the date the sample was collected.

Respiratory Specimens

A. Lower respiratory tract

Bronchoalveolar lavage, tracheal aspirate, or pleural fluid

- Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.
- Refrigerate specimen at 2-8°C if the specimen will arrive at the testing laboratory within 72 hours of collection; if exceeding 72 hours, freeze at -70°C and ship on dry ice.

Sputum

- o Have the patient rinse his/her mouth with water and then expectorate (deep cough) sputum directly into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.
- o Refrigerate specimen at 2-8°C if the specimen will arrive at the testing laboratory within 72

hours of collection; if exceeding 72 hours, freeze at -70°C and ship on dry ice.

B. Upper respiratory tract

Nasopharyngeal AND oropharyngeal swabs (NP/OP swabs)

- Collection of both nasopharyngeal and oropharyngeal swabs, or a combined NP/OP specimen, is recommended.
- Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing.
- Collection technique
 - Nasopharyngeal swabs: Insert a swab into the nostril parallel to the palate. Leave the swab in place for a few seconds to absorb secretions. Swab both nasopharyngeal areas.
 - Oropharyngeal swabs: Swab the posterior pharynx, avoiding the tongue.
- Place swabs immediately into sterile tubes containing 2-3 ml of viral transport media. NP/OP specimens can be combined, placing both swabs in the same vial.
- Refrigerate specimen at 2-8°C if the specimen will arrive at the testing laboratory within 72 hours of collection; if exceeding 72 hours, freeze at -70°C and ship on dry ice.

Nasopharyngeal wash/aspirate or nasal aspirates

- Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.
- Refrigerate specimen at 2-8°C if the specimen will arrive at the testing laboratory within 72 hours of collection; if exceeding 72 hours, freeze at -70°C and ship on dry ice.

Serum

Serum (for serologic testing at CDC) [Note: Use this serum guidance if the only serum specimen available would be collected 14 or more days after illness onset]

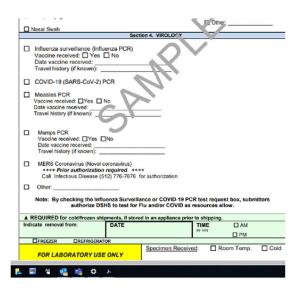
Serum (for rRT-PCR testing at authorized state or local public health lab) [Note: Use this serum guidance for specimens collected during the first two weeks of the patient's illness onset]

- o For rRT-PCR testing (i.e., detection of the virus and not antibodies), a single serum specimen collected optimally during the first 10-12 days after symptom onset is recommended.
- The minimum amount of serum required for SARS-CoV-2 testing (either serologic or rRT-PCR) is 200 μL. If both SARS-CoV-2 serology and rRT-PCR tests are planned, the minimum amount of serum required is 400 μL (200 μL for each test). Serum separator tubes should be stored upright for at least 30 minutes, and then centrifuged at 1000–1300 relative centrifugal force (RCF) for 10 minutes before removing the serum and placing it in a separate sterile tube for shipping (such as a cryovial). Refrigerate the serum specimen at 2-8°C and ship on ice-pack; freezing and shipment of serum on dry ice is permissible.
- Children and adults
 - Collect 1 tube (5-10 mL) of whole blood in a serum separator tube.
- o Infants
 - A minimum of 1 mL of whole blood is needed for testing pediatric patients.
 - If possible, collect 1 mL in a serum separator tube.

Submission Forms

For PCR testing:

Use DSHS Laboratory G-2V Specimen Submission Form for specimen submission. On the form, under the Virology section, check the box "COVID-19 (SARS-CoV-2)".



Make sure the patient's name and approved secondary identifier on the form exactly match what is written on the specimen tube.

An approved secondary identifier should be one of the following: date of birth, medical record number, social security number, Medicaid number, or CDC number.

Fill in the patient's first name, last name, address, city, state, zip code, sex, date of birth, date and time of collection, date of onset and diagnosis/symptoms.

The submitter will not incur a cost for novel coronavirus testing when patients meet testing criteria as long as the appropriate payor source is selected on the submission form. Contact DSHS EAIDU at 512-776-7676 for instructions on filling out the Payor Source section of the G-2V Specimen Submission Form.

For Whole Genome Sequencing (WGS)

Use DSHS Laboratory whole genome sequencing line list form, which is distributed to submitters upon sequencing approval.

Fill in the patient's first name, last name, date of birth, address, city, state, zip code, gender, date and



<u>time</u> of collection, patient contact information, sample ID, date collected, sample source, transport medium, Ct value and reason for sequencing.

Enclose a printed copy with sample shipment <u>and</u> email an electronic copy of the completed line list to <u>wgs.dshs@dshs.texas.gov</u> and <u>EAIDU-Coronavirus@dshs.texas.gov</u> with expected date of delivery and tracking number for package.

Specimen Shipping

Notify the testing laboratory that you will be shipping the specimen and provide the shipment date, tracking number, and all relevant forms.

Transport temperature: Store the specimen at 2-8°C if the specimen will be received at the laboratory within 72 hours of collection; ship the specimen on cold or freezer packs. Otherwise, the specimen must be frozen at -70°C and shipped on dry ice.

Ship specimens via overnight delivery.

DO NOT mail on a Friday or the day before a holiday unless special arrangements have been made in advance with the DSHS Laboratory.

Ship specimens to:

Laboratory Services Section, MC-1947 Texas Department of State Health Services Attn. Walter Douglass (512) 776-7569 1100 West 49th Street Austin, TX 78756-3199

Causes for Rejection:

Incorrect source of specimen

The specimen is received at an incorrect temperature, such as ambient temperature

The specimen is received more than 72 hours after collection (if refrigerated)

Missing or discrepant information on form/specimen

Patient does not meet testing criteria or has not been approved for testing by EAIDU Coronavirus Epidemiology Team (<u>EAIDU-Coronavirus@dshs.texas.gov</u>).

REVISION HISTORY

January 2022

Section established in EAIDG and all sections written to reflect current guidelines for COVID-19 reporting, prevention, and testing information. Guidance for COVID-19 is rapidly evolving, please see the www.dshs.texas.gov/covid-19-coronavirus-disease-2019/information-public-health webpage for the most up to date information.

January 2023

Updates made to entire section