

COVID-19 Next Generation Sequencing Specimen Collection and Submission Instructions

<p>Coordination with Epidemiologists</p>	<p>Providers interested in submitting samples for SARS-CoV-2 next generation sequencing (NGS) must coordinate with their Local and/or Regional Public Health Department (https://www.dshs.texas.gov/regions/2019-nCoV-Local-Health-Entities/). Local and Regional Public Health Departments must seek sequencing approval from Texas DSHS Eaidu epidemiologists (Eaidu-Coronavirus@dshs.texas.gov) to initiate the submission process.</p> <p><u>Criteria for Prioritized Specimens</u></p> <ol style="list-style-type: none"> a. Specimens from patients who already have a positive COVID-19 PCR lab result; a PCR positive sample must be available for sequencing b. Priority specimens for <u>reinfection evaluation</u> include the following: <ul style="list-style-type: none"> • Specimens from symptomatic or asymptomatic COVID-19 patients who have 2 positive PCR tests separated by at least 90 days and stored clinical samples or RNA extracts are available for both tests c. Priority specimens for <u>genetic variant surveillance</u> include the following: <ul style="list-style-type: none"> • Symptomatic or asymptomatic COVID-19 patients who are close contacts with a case of known infection with a SARS-CoV-2 genetic variant of concern • Patients with a history of international travel to a location where there is known, or suspected, community spread of one or more SARS-CoV-2 genetic variants of concern • Patients with an extremely severe or unusual COVID-19 illness presentation • Patients who are fully vaccinated with an FDA authorized COVID-19 vaccine, with the most recent dose occurring at least 2 weeks prior to illness onset and no SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected <45 days before the most recent positive test. • Patients who developed COVID-19 in congregate living settings with attack rates over 75% within a 2-week period, where up to 5 samples will be sequenced per outbreak • Other outbreak specimens where there is reason to suspect an infection with a SARS-CoV-2 genetic variant of concern. • Specimens from COVID-19 associated pediatric deaths • Specimens from potential reinfections with at least 2 positive PCR results that meet all other sequencing criteria (this includes samples where initial positive PCR test sample is unavailable)
<p>Specimen Types</p>	<ul style="list-style-type: none"> • All specimens submitted for Next Generation Sequencing (NGS) must have been previously tested by PCR methods and confirmed to be positive for COVID-19 • The PCR results should have target gene PCR CT value of ≤ 30 • The ONLY samples that can be sequenced with CT values > 30 are vaccine breakthrough and reinfection cases <p><u>RNA Extracts (preferred)</u></p> <ul style="list-style-type: none"> • minimum volume required: 30 μl <p><u>Clinical Specimens</u></p> <ul style="list-style-type: none"> • Nasopharyngeal (NP) swabs in viral transport media (VTM) • Oropharyngeal (OP) swabs and Nasal swabs are also acceptable • Specimen collected in Universal Transport Media (UTM), Amies, or 0.85% Saline are also acceptable • Minimum volume required: 0.8 mL (volume as low as 0.4mL may be accepted for testing but may not be sufficient for completion of all tests required)

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Specimen Collection, Handling, and Shipping

- **RNA extracts and clinical specimens should be stored frozen at -70°C and must be shipped frozen on dry ice for overnight delivery.**
- Complete the line list. All fields marked with an asterisk (*) must be filled. Ship the specimens with a hard copy of the completed line list to the DSHS Laboratory.
- **If sending both RNA extracts and clinical specimens in the same shipment, enter all RNA extract specimen information at the top of the line list followed by clinical specimen information.**
- Label the tubes with the specimen ID and date of collection. The identifiers on the tubes must match those entered on the line list.
- If sending RNA extracts and clinical specimens in same shipment, please put RNA extracts and clinical specimens in separate biohazard bags.
- Maintain proper infection control when handling specimens. Guidance can be found at <https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html#a4>.
- If shipping specimens through a courier, specimens may be shipped Monday-Thursday for receipt at the DSHS Laboratory Tuesday-Friday. Weekend delivery will be considered on a case by case basis and requires pre-approval by DSHS. Contact EAIDU epidemiologists for pre-approval.
- Place the specimen container in a zip-lock style biohazard bag and securely seal the bag. Place a hardcopy of the line list in the outer sleeve of the bag or attach it to the outside of the bag (Note: **DO NOT** seal the line list inside the biohazard bag with the specimen as we cannot process potentially contaminated forms). Put the bag or bags in a Styrofoam insulated cardboard box for shipping.
- Follow international Air Transportation Regulations for shipping of Category “B” Biological Substances - Infectious Subs. brochure - PHMSA.
- Ship to the physical address: TX DSHS Laboratory Services, ATTN: Walter Douglass 512-776-7569, 1100 W. 49th Street, Austin TX, 78756.
- **Record and send the shipping tracking number and an electronic copy of the completed line list by email to wqs.dshs@dshs.texas.gov with the expected delivery date.**
- Samples received with missing information or without submitting facility information may be unsatisfactory for testing if missing information not received within 3 working days of receipt

Results Reporting

- If the submitter/provider requests the results, the results will be added to the submitted line list and emailed back to the submitter by the DSHS Laboratory.