

Testing and Sequencing SARS-CoV-2 Specimens at PHEL

Guidelines for Clinical and Commercial Laboratories

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SARS-CoV-2 Testing Criteria

Testing for SARS -CoV-2 will only be performed on specimens collected from patients who meet the current criteria for testing put forth by New Jersey's Communicable Disease Service.

- NJ PHEL provides **diagnostic testing** for COVID-19 (SARS-CoV-2 RT-PCR) to facilities supported under the state's vulnerable populations initiative. If your facility is in need of laboratory testing which cannot be acquired through another source such as a commercial laboratory, please reach out to phel.influenza@doh.nj.gov. Specimen submission must be pre-approved by NJ PHEL prior to testing.
- NJ PHEL provides SARS-CoV-2 variant identification by whole genome sequencing for surveillance purposes only. Currently, NJ PHEL is only testing surveillance specimens submitted by sentinel hospital sites. If your facility is interested in becoming a surveillance site, please contact sars.sequencing@doh.nj.gov. This testing is being performed for epidemiological surveillance purposes only. Per current CMS guidelines individual patient results will not be reported to submitters.



Specimen Collection and Storage

Specimen Collection

- Collect specimens aseptically as soon as possible after symptom onset or at autopsy.
- Refer to the CDC guidelines available here for current specimen collection recommendations.
- For detailed instructions on how to collect respiratory specimens see here: Respiratory Specimen Collection
- Proper infection control practices should be followed during specimen collection.
- Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts.

• Preferred specimen type:

- Upper respiratory swab (Nasopharyngeal (NP), Nasal Mid-Turbinate (NMT) or anterior nasal, placed in a transport tube containing 1-3 mL viral transport media.
- Hologic Panther Aptima Direct Load Tubes- These tubes are provided directly by PHEL specifically for use at PHEL and cannot be run on any other testing platform. Contact phel.mmu@doh.nj.gov to request tubes. If collecting specimens in these tubes, you MUST use the salmon-colored swab included in the provided collection kit, any other swab types noted in the tube upon receipt will be rejected.

Other acceptable specimen types:

- Oropharyngeal swab- CDC recommends collecting only the NP specimen, although an OP specimen is an acceptable specimen type. If both NP and OP specimens are collected, combine them in a single tube.
- Nasopharyngeal wash/aspirate or nasal wash/aspirate
- Bronchoalveolar lavage, tracheal aspirate, pleural fluid, lung biopsy
- Swabs collected into Amies transport medium or sterile saline

Note: Saliva and sputum are not acceptable specimens for testing at PHEL and will be rejected.

Specimen Storage

- Diagnostic specimens can be stored at 2-8°C for up to 72 hours after collection. Specimens not received refrigerated within the 72-hour window will be rejected.
- If testing is expected to occur after 72 hours of collection, store specimens frozen at -70°C or below and ship on dry ice.
 - Specimens frozen at -20°C or below will be accepted, but this could result in sample degradation and specimen may not be acceptable quality for testing.



SARS-CoV-2 Whole Genome Sequencing- Variant Identification

NJ PHEL provides whole genome sequencing for SARS-CoV-2 variant identification for epidemiological and surveillance purposes only.

This testing is for public health surveillance efforts and will not replace any diagnostic testing currently performed in commercial laboratories, hospitals or other healthcare settings. Surveillance specimens will be screened for SARS-CoV-2 by RT-PCR prior to sequencing and may also be referred to the Centers for Disease Control and Prevention for further characterization.

If your facility is interested in becoming a surveillance site, please contact sars.sequencing@doh.nj.gov

- Per current CMS guidelines individual patient results will not be reported to submitters.
- (For more information refer to CMS FAQ here: https://www.cms.gov/files/document/clia-sars-cov-2-variant.pdf).

Submitting Samples for SARS-CoV-2 Whole Genome Sequencing- Variant Identification

If your facility is requested to provide samples for variant surveillance to PHEL:

- Submit 5-10 <u>SARS-CoV-2 positive samples</u> weekly.
- Acceptable specimen types are listed above (NP, NMT or nasal swab in VTM is preferred).
- Sequencing success is limited by the quality of the specimens. When selecting specimens for sequencing, please submit samples with the following characteristics wherever possible:
 - An RT-PCR Ct value of ≤28. If Ct values are not available, specimens that are clearly positive for SARS-CoV-2 may be sent.
 - Collected or tested within the last 7 days.
 - Specimens should not have been independently sequenced to avoid duplication of sequence data submitted to public databases.
 - Once collected, specimens can be stored at 2-8°C for no more than 72 hours. If the sample cannot be collected and shipped within 72 hours, they must be frozen at ≤ -70°C and shipped on dry ice.
 - Specimens frozen at -20°C or below will be accepted, but this could result in sample degradation and specimen may not yield sequencing results.
- The test request which should be checked is 'SARS-CoV-2 Whole Genome Sequencing- Variant Identification'



Test Ordering and Specimen Submission

Specimen Labeling

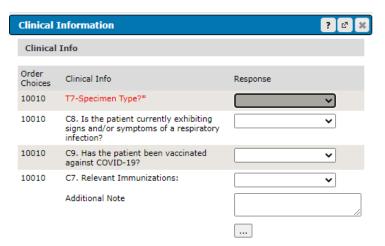
- Label each specimen with a minimum of two patient identifiers (e.g. the patient's name and date of birth). Ensure the patient's name and DOB matches the specimen label **exactly**.
- When possible, test requests should be submitted electronically through our Online Ordering and Reporting portal. For a quick reference guide to using the portal, see How To Order Respiratory Testing Online
 - To gain access to the online portal, please see instructions located here.
- If you are unable to order test requests electronically, please fill out our current paper requisition form (SRD-1) here.
- A copy of test requisition form should accompany each specimen.
- Refer to sections below for detailed instructions on ordering test requests for SARS-CoV-2
 Diagnostic Testing and SARS-CoV-2 Variant Identification.

How to order a Test Request: SARS-CoV-2 Diagnostic Testing

 To request SARS-CoV-2 diagnostic testing, please check the request "SARS-CoV-2 Diagnostic Testing (10010)"



- Add the selected test then save.
- Fill out the required fields marked with a red asterisk:



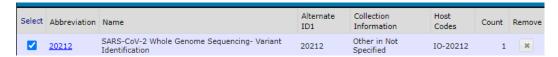
After filling out any additional relevant information, click "Save" to save the test order.



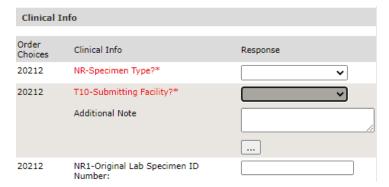
• Print the requisition form which automatically pops up and pair the samples with their requisition forms in the package to be sent to PHEL. Do not place requisition forms directly in contact with specimen tubes in case a tube leaks or breaks in transit.

How to order a Test Request: SARS-CoV-2 Whole Genome Sequencing- Variant Identification

 To request SARS-CoV-2 Sequencing/Variant Identification Testing, please check the request "SARS-CoV-2 Whole Genome Sequencing- Variant Identification (20212)"



- Add the selected test then save.
- Fill out the required fields marked with a red asterisk:



- Under submitting facility, select your facility name. If you do not see your facility listed, simply mark 'Other', and write-in your name in the comments field below.
- After filling out any additional relevant information, click "Save" to save the test order.
- Print the requisition form which automatically pops up and pair the samples with their requisition forms in the package to be sent to PHEL. Do not place requisition forms directly in contact with specimen tubes in case a tube leaks or breaks in transit.

Specimen Shipping to PHEL

- Specimens may be shipped to the laboratory for receipt Monday- Friday from 8am 5pm. NJ PHEL is closed on weekends and state holidays.
- For detailed instructions on how to ship specimens to PHEL, please refer to our guidelines available here.
- Questions regarding shipping to the laboratory can be directed to <u>PHEL.SpecimenReceiving@doh.nj.gov</u>