SARS-CoV-2 Testing for Coronavirus Disease 2019 (COVID-19)
Updated December 14, 2021

This NJ PHEL Supplemental Technical Bulletin 21.2.0 supersedes NJ PHEL Technical Bulletin 21.1 providing updated guidance regarding laboratory testing for SARS-CoV-2 (the virus that causes COVID-19), including revised submission guidance for diagnostic specimens and information concerning variant surveillance.

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. Turn-around time for testing will be dependent on testing volumes. Information about the interpretations of findings per EUA guidelines will accompany the test result.

Update: Submission of Samples for Variant Detection- Omicron variant

New in this update:

- On 26 November 2021, the World Health Organization (WHO) designated the variant B.1.1.529 a variant of concern (VOC). This variant has been given the name Omicron.
- Omicron is a highly divergent variant with a high number of mutations, including 26-32 nucleotides in the spike gene. Some of these mutations are concerning and may be associated with the potential for immune escape and higher transmissibility. There are currently considerable uncertainties as to the impact of these mutations on transmission, vaccine effectiveness or clinical disease severity. Further study is required.

- Due to the Omicron deletion mutation of 2 nucleotides, several assays including the commonly used ThermoFisher TaqPath PCR assay, cannot detect the S gene of the variant, causing an S gene target failure (SGTF). A full list of impacted assays can be found here: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests

- The implications of SGTF mean that these assays can be used for screening of samples to detect potential omicron variant. The SGTF does not impact the assays' ability to detect COVID-19 in clinical samples. Samples that are positive for omicron variant being tested on ThermoFisher TaqPath assay will be positive for the N and Orf1ab gene targets.

- Any laboratories using one of these assays may submit the specimens meeting the criteria below to PHEL for sequencing.
    - **"NEW " S Gene Target Failure (SGTF) Specimens defined as:**
        - **Ct of <28 for the other gene targets, and NO DETECTION of the S gene target.** (*If the specimen has target Ct values >28 and fails to amplify the S gene target, please DO NOT submit these specimens as the lack of the S gene signal may be due to low viral concentration rather than S gene mutations.)*
- A complete, updated listing of priority variants identified by the CDC can be found here: https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html

- Added additional information on how to submit samples to PHEL using the Online Electronic Ordering and Reporting Portal

Instructions for Submission of Samples for Variant Identification and Surveillance

NJDOH requests specimens be sent for sequencing ONLY if they meet one of the following criteria:

Criteria #1: Recent travel to and/or from countries outside the United States that have reported an emerging variant of concern not currently circulating in the United States, or close contacts of cases associated with such travel

Criteria #2: Suspected reinfection (recurrence of symptoms) and positive test result >90 days after the initial RT-PCR positive test result (not antigen or serology)

Criteria #3: Cases associated with an **outbreak or cluster** of concern

Criteria #4: Vaccine breakthrough case defined as a U.S. resident who has SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected >14 days after completing the primary series of an FDA-authorized COVID-19 vaccine.

Criteria #5: S Gene Target Failure (SGTF) samples which display clear positivity on other SARS-CoV-2 gene targets with a Ct value of ≤28, and no positivity on the S gene target.

This testing is being performed for epidemiological surveillance purposes only. 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)

- If a variant of concern is identified, results will be reported to state and local public health agencies. Local public health agencies may inform providers of results for public health follow up as appropriate
- Due to limited sequencing capacity, only a subset of the submitted specimens may be sequenced.

General information on specimen submission:

1. Refer to the PHEL Technical Bulletin below for general guidance on specimen collection, labeling, storage, and shipping.

2. Submit only specimens with an RT-PCR Ct value of ≤28, if known/available

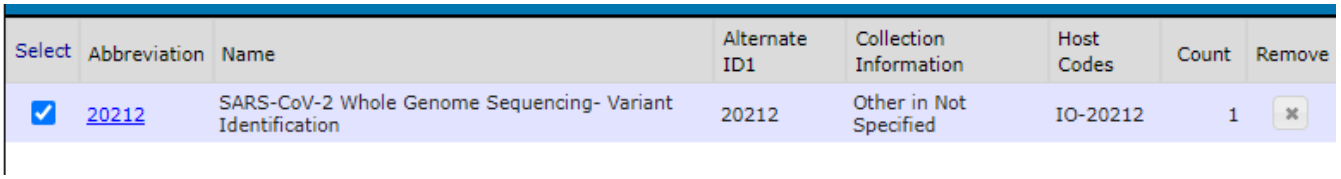
3. Store respiratory specimens at 2-8°C for up to 72 hours after collection. If a delay in testing or shipping is expected, specimens must be stored at -70°C or below and shipped on dry ice.

    - If samples have been refrigerated for greater than 72 hours after time of collection, consider collecting a new specimen for submission.
    - Samples not on dry ice received more than 72 hours after collection will be rejected.

4. **Each sample** must be received with a requisition form that indicates the test requested and the reason for sequencing **(clearly indicating criteria #1-5 above)**

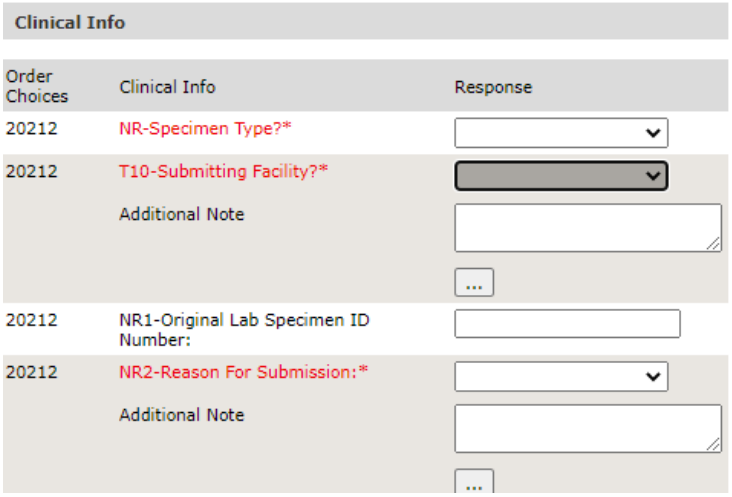
How to submit a sequencing/variant identification sample in PHEL's Online Ordering and Reporting Portal:

1. If your facility has access to a PHEL Online Ordering and Reporting account and needs to submit a sample for sequencing/variant identification, select the order choice "SARS-CoV-2 Whole Genome Sequencing: Variant Identification



Select	Abbreviation	Name	Alternate ID1	Collection Information	Host Codes	Count	Remove
☑	20212	SARS-CoV-2 Whole Genome Sequencing- Variant Identification	20212	Other in Not Specified	IO-20212	1	✖

2. Fill out the required fields marked with a red asterisk

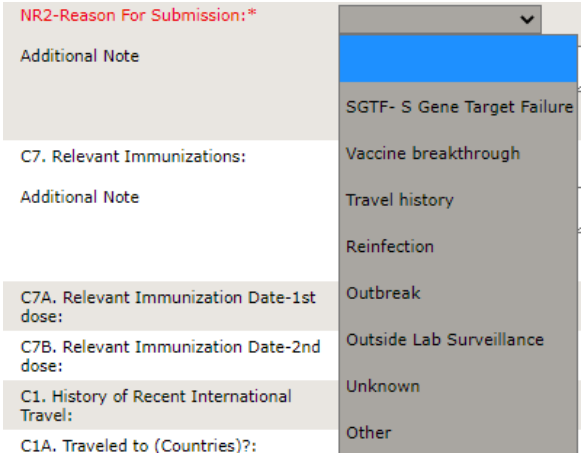


Clinical Info

Order Choices	Clinical Info	Response
20212	NR-Specimen Type?*	
20212	T10-Submitting Facility?*	
	Additional Note	
20212	NR1-Original Lab Specimen ID Number:	
20212	NR2-Reason For Submission:*	
	Additional Note	

Under submitting facility, if you do not see your facility listed, simply mark 'Other'.

3. Select one of the criteria above as the reason for submission.



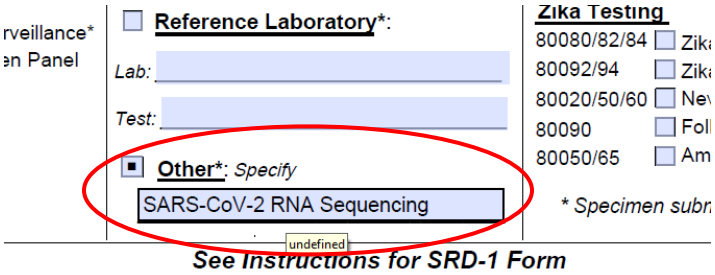
***N.B.** if your laboratory does not participate in a specific PHEL surveillance COVID program, or has not been instructed by the state Communicable Disease Service to send a sample, **the Reason for Submission MUST be one of the criteria listed above**

4. Fill out any additional information, such as immunization or travel history, if applicable and available.

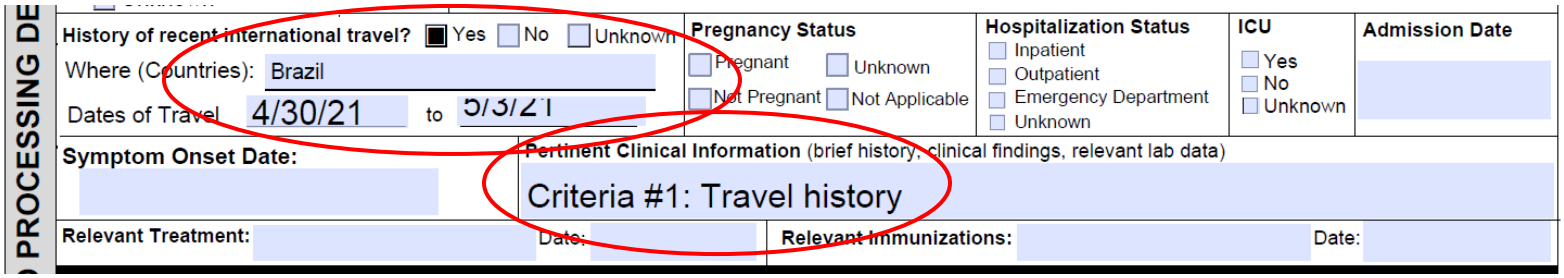
5. Click save and then print the requisition form which automatically pops up. Pair the samples with their requisition forms in the package to be sent to PHEL. Do not place requisition forms directly in contact with specimen tubes in case a tube leaks or breaks in transit.

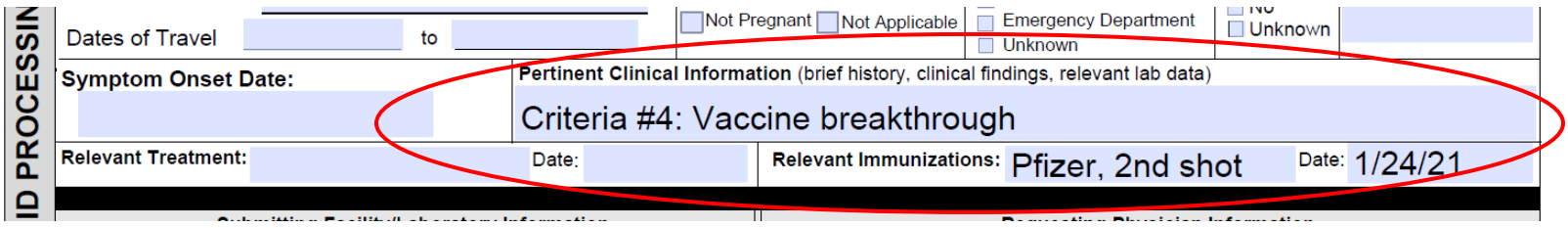
How to submit a sequencing/variant identification sample on a paper SRD-1 requisition form:

1. Check other category and write-in SARS-CoV-2 RNA Sequencing for the test requested

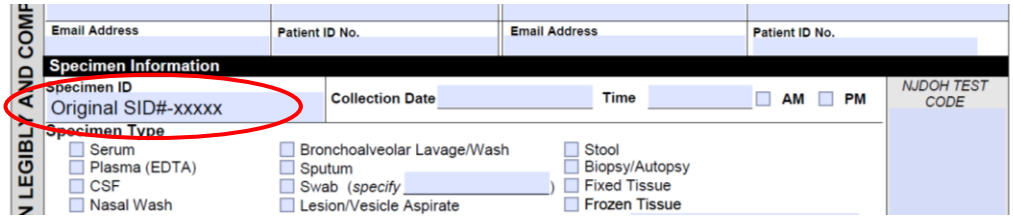


2. **CLEARLY INDICATE the criteria for submission above (#1-5) in the pertinent clinical information section (examples below)**
   a. Criteria #1, #2 and #5 may be submitted without pre-approval
   b. Criteria #3 and #4- **Contact the local health department** to notify of a possible case (A directory of local health departments is available at www.localhealth.nj.gov.)

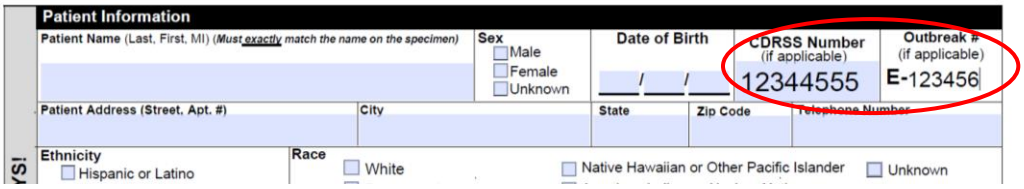




3. **If known**, write the original testing laboratory's specimen ID number in the Specimen ID field



4. **If applicable**, include the CDRSS case number, outbreak number (E#) or investigation number (I#)



5. Send an email to SARS.Sequencing@doh.nj.gov upon shipping a specimen for sequencing with the number of samples being shipped, reason for shipping and estimated date/time of delivery.

References and Resources:

https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html (CDC variant definitions)

https://covid.cdc.gov/covid-data-tracker/#variant-proportions (Proportions of cases caused by variants)

Guidance for Specimen Collection, Labeling, Storage and Shipping:

For diagnostic testing for COVID-19, CDC recommends collecting and testing an upper respiratory specimen.
Acceptable specimen types include:

- A nasopharyngeal (NP) or oropharyngeal swab collected by a healthcare professional
- Nasopharyngeal wash/aspirate, nasal wash/aspirate, tracheal aspirate or bronchoalveolar lavage collected by a healthcare professional
- A nasal mid-turbinate (NMT) swab collected by a healthcare professional or by onsite self-collection (using a flocked tapered swab)
- An anterior nares specimen collected by a healthcare professional or by onsite self-collection (using a round foam swab). For NS, a single polyester swab with a plastic shaft should be used to sample both nares.

Swabs should be placed in a transport tube containing either viral transport medium, Amies transport medium, or sterile saline.

- 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. Place swabs immediately into sterile tubes containing 1-3 ml of viral transport media.
- PHEL does not accept saliva or sputum as an acceptable specimen type for testing
- Maintain proper infection control when collecting specimens. Refer to the CDC guidelines on specimen collection for further details: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

Refrigerate specimens at 2-8°C for up to 72 hours post-collection. Ship specimens with frozen cold packs to maintain 2-8°C.

- If delivery will occur more than 72 hours after collection, specimen should be frozen at -70°C or below and ship on dry ice

Label each specimen with the patient's name and date of birth. A copy of test requisition form (if test is ordered online) or a completed SRD-1 submission form should accompany each specimen

1. Complete an SRD-1 form for each specimen submitted. Fill out the form as completely as possible.
2. Ensure the patient's name and DOB matches the specimen label exactly.
3. Record date and time of collection and specimen type.
4. Check the appropriate test type for the specimen requested
5. Make sure all physician and clinical laboratory information is accurate to avoid delays in reporting.

Specimen Rejection Criteria:

- **Specimens >72 hrs. after collection that are not received frozen on dry ice**
- **Unlabeled specimens**
- **Incomplete specimen labeling or documentation (specimens MUST have an accompanying COPIA test requisition form or SRD-1 form with two patient identifiers that match the specimen label.**
- **Specimen leaked from container during transit**
- **Insufficient specimen volume for testing**
- **Inappropriate specimen type**

Packaging and Shipping:

1. Package, ship and transport specimens as Category B Infectious Substances according to International Air Transport Association (IATA) Packaging Instruction 650.
2. Ship refrigerated specimens for overnight (24 hour) delivery to NJ PHEL on frozen cold packs.
3. If a specimen is frozen at -70°C, ship specimens for overnight (24 hour) delivery on dry ice.
4. Arrange for shipments to arrive **between the hours of 8am to 5pm on Monday-Friday** to the following address:

   New Jersey Department of Health
   Public Health and Environmental Laboratories
   3 Schwarzkopf Drive Ewing, NJ 08628
   ATTN: SPECIMEN RECEIVING: CoV-2

5. Additional useful and detailed information on packing, shipping, and transporting specimens can be found at Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV).
6. If there are questions regarding how to submit specimens to the laboratory or to arrange for Friday, Saturday, Sunday or holiday delivery, please contact the laboratory at Tel: (609)-530-8387 or Email: Virology.PHEL@doh.nj.gov

Expected Turn Around Times for SARS-CoV-2 Testing Performed at NJ PHEL

The optimal turnaround time based on concurrent testing volumes is within 48 hours for samples received and accessioned before 2:30 pm on weekdays.

If specimens are received after 2:30pm on Friday or over a weekend/holiday, the expected turnaround may not be until COB on the following Monday

For Weekend/After-Hours Specimen Arrivals

Providers are encouraged to assure that your shipments arrive during regular business hours (Monday - Friday 8AM- 5PM). Although special provisions to receive specimens after hours are discouraged, the NJPHEL recognizes that under emergency conditions this may be required. There is a refrigerator located outside the receiving laboratory where specimens can be dropped off during off-hours (see directions below).

If delivery is required to occur after-hours or on weekends/holidays, please contact the receiving laboratory Tel: (609)-530-8387 or Email: Virology.PHEL@doh.nj.gov to arrange delivery.

Instructions for Deliveries to PHEL via Private Courier

1. Use **GPS address of 1040 River Road**, which brings the driver to main gate of NJ State Police.

2. The side gate is closed on weekdays after 6pm and all day on weekends. The guard should be able to direct the driver to our building (5-story glass building- toward the back of the campus and the largest building- follow the yellow signs for PHEAL).

3. Once on the State Police HQ Campus (GPS: 1040 River Rd. Ewing, NJ) and approaching the PHEAL building (5-story glass building), follow signs directing deliveries to the BACK of the building. DO NOT DELIVER SAMPLES TO THE FRONT ENTRANCE.

4. Press the button at the liftgate and speak with security to be allowed through.

5. Follow the road along the back of the building to the loading dock. The loading dock is at the end of the building. DO NOT STOP HALFWAY to deliver the specimens to the agriculture door or refrigerator that is signified by the Red-X on the map below. Drive past the green house on the right and proceed to the loading dock at the end.

6. Park and walk into the building through gray doors marked by the check mark on the map.

7. Once in the building, drivers will use the phone in the hallway to call 364. Specimen receiving staff will answer the phone and come out to receive the specimens during normal business hours.

8. If there is no answer or it is outside of normal working hours (8:00-5:00), they are to deliver the specimens to the refrigerator in this hallway (the fridge is white and has a double door).
   ***There is a sign near the phone as to the number to call, and a sign on the refrigerator that it is where the coronavirus specimens should be placed when delivered**.

9. If delivery persons are unsure of the delivery location, they should call 609-530-8387 to speak with specimen receiving staff.

NOTES ON PACKAGING AND SHIPPING CATEGORY B INFECTIOUS SUBSTANCES

USDOT Link to Category B Packaging Instruction 49 CFR 173.199

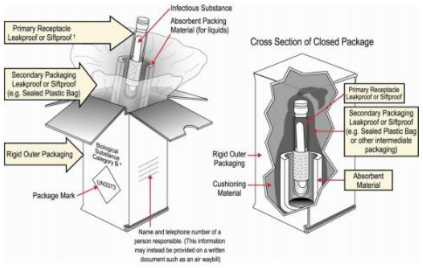
Above is a link to the USDOT packaging instruction for Category B Infectious Substances. The proper shipping name is "Biological Substance, Category B (UN3373)". The proper shipping name and number MUST appear on all paperwork and on the outside of the package. UN diamond shaped certified USDOT hazardous substance labels MUST be used on the outer package on the overpack, if an overpack is required.

1. **No training certification is required for shippers if only shipping Category B**. The regulations do require that the shipper follow IATA 650 or USDOT 173.199 packaging instructions. If a shipper ships both Category A and B, they must be certified every 2 years.
2. **Category B packaging instruction from USDOT 173.199 (link) is the same as IATA packaging instruction 650 EXCEPT that for AIR carriage the following also applies:**

    a. **Airway bill - as well as the outer packaging must contain the words "Biological Substance, Category B (UN 3373)"** Proper shipping name and UN number.
    b. **There are volume limits if transporting by air.** The primary receptacle must be leakproof and not contain more than 1L. If using an Overpack, the outer packaging must not contain more than 4 L.
    c. **The primary container or secondary packaging must be able to withstand changes in air pressure of 95 kPa.** These can be the Tyvek bags which are marked as such OR, you can use the Category A packaging kit, which contains a secondary screwcap container which is certified for air transport.
    d. **If it is necessary to ship on dry ice, the dry ice packaging instructions for air also apply** (volume limits for ground and air differ) Dry ice packaging instructions do NOT apply to frozen cold packs. Use of a refrigerated or frozen outer container is required for both frozen cold packs and dry ice, but dry ice is a Dangerous Good, just like Category A, and requires a UN Certified packaging, marking and labelling, so best to use the Category A kit for dry ice marked Class 6.2, even if shipping Category B.

3. **NOTE: No Shippers Declaration of Dangerous Goods is required for Category B or dry ice (if a specific protocol suggests use of dry ice). The weight of the dry ice, and the proper shipping name and UN numbers must appear on the airway bill and must not exceed 2.3 Kg (5 pounds).**

UN 3373 Category B schematic for packaging



CDC Website:
https://www.cdc.gov/coronavirus/mers/downloads/lab/UN3373-packaging-schema.pdf

If it is necessary to use dry ice Overpack label:

https://www.cdc.gov/coronavirus/mers/downloads/lab/UN3373-label-dry-ice.pdf

Important Links:

- **Information on Laboratory Testing for SARS-CoV-2** : https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html
- **For LABORATORY questions regarding SARS-CoV2 testing at NJ PHEL**: Email the PHEL Virology Team at: Virology.PHEL@doh.nj.gov or visit the PHEL webpage at http://www.nj.gov/health/phel/
- **For general NJPHEL information**, call: (609)-530-8516 Monday-Friday, 9:00AM to 5:00 PM.
- **For CLINICAL guidance, see the NJDOH Communicable Disease Service Coronavirus webpage:** https://www.nj.gov/health/cd/topics/ncov.shtml
- **Biosafety Guidelines for Handling and Processing Laboratory Specimens (CDC):**https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html
- **Specimen Collection Guidelines, including packaging and shipping** https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
- **Link to CDC Form 50.34:** https://www.cdc.gov/laboratory/specimen-submission/form.html
- **Link to NJ PHEL SRD-1 Form**: https://www.nj.gov/health/forms/srd-1.pdf