

SARS-CoV-2 Testing for Coronavirus Disease 2019 (COVID-19) Update April 3, 2020

This NJ PHEL Supplemental Technical Bulletin 20.1.5 supersedes NJ PHEL Technical Bulletin 20.1.4 providing updated guidance regarding laboratory testing for SARS-CoV-2 (the virus that causes COVID-19).

NJ PHEL has completed verification of the CDC real-time RT PCR diagnostic panel for SARS-CoV-2 which was granted Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) <https://www.fda.gov/media/134919/download>. **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 will accompany the test result.

For more information on COVID-19: <https://www.cdc.gov/coronavirus/2019-ncov/about/index.html>

Update for April 3, 2020

Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens

NEW: For initial diagnostic testing for COVID-19, CDC recommends collecting and testing an upper respiratory specimen. Nasopharyngeal specimen is the preferred choice for swab-based SARS-CoV-2 testing. When collection of a nasopharyngeal swab is not possible, the following are acceptable alternatives:

- An oropharyngeal (OP) specimen collected by a healthcare professional, or
- A nasal mid-turbinate (NMT) swab collected by a healthcare professional or by onsite self-collection (using a flocked tapered swab), or
- 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.

- If both NP and OP swabs both are collected, they should be combined in a single tube to maximize test sensitivity and limit testing resources.
- 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.
- Specimens should be collected as soon as possible once a decision has been made to pursue COVID-19 testing, regardless of the time of symptom onset. Maintain [proper infection control](#) when collecting specimens.

Reference: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

Commercial Laboratory Testing for SARS-CoV-2

Several Commercial laboratories are now providing testing for SARS CoV-2 under an FDA-EUA.

Samples may be sent for testing to a reference laboratory that performs this test under an EUA from the FDA, instead of NJ PHEL. No approval or PUI number is required.

See NJ Clinical Laboratory Improvement Services Licensure information [here](#)

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

SARS-CoV2 tests will be performed at the NJPHEL as received during regular business hours (Monday-Friday 8AM- 5PM). PHEL testing is being provided on weekends.

For Samples Received on Weekdays:

The optimal turnaround time based on concurrent testing volumes is within 24 hours for samples received and accessioned before 2:30 pm on weekdays.

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.

For Weekend/After-Hours Specimen Arrivals

Since PHEL is testing on weekend days, if you can use your own courier to transport the specimens to PHEL, the security guard will allow entrance to the loading dock area in the back of our building. The courier will go through the double doors and use the posted number to call specimen receiving staff. For after-hours deliveries when receiving staff is not available, the delivery may be left in the labeled refrigerator to the left of the loading bay doors.

- If the specimen box has arrived Saturday or Sunday morning before the analyst starts their run, these specimens will be included in the run and the results will be available the next morning by approximately 11am.
- If the specimen box arrives on Saturday or Sunday after the analyst starts their run, then these specimens will be included in the next day's run and the results will be available by 11 am the day after.

For Deliveries to PHEL via Private Courier

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

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). Once on campus and approaching the building, they can use the attached directions as to where they should deliver specimens. Fridges are labeled as to where COVID/Coronavirus specimens should go based for business hours or after-hours deliveries.

NEW: Instructions for Delivery of COVID-19/Coronavirus Specimens once on State Police HQ Campus:

1. 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.
 2. Press the button at the liftgate and speak with security to be allowed through.
 3. 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.
 4. Park and walk into the building through gray doors marked by the check mark on the map.
 5. 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.
 6. 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.
- If delivery persons are unsure of the delivery location, they should call 609-530-8387 to speak with specimen receiving staff.



Additional Guidance for Specimen Collection, Labeling, Storage and Shipping:

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. For shipments going to PHEL on Monday-Thursday, Ship to this address:

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

5. 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 (Tel: (609)-530-8516 or Email: Virology.PHEL@doh.nj.gov)

Specimen Rejection Criteria:

- **Specimens not kept at 2-8°C (≤72 hrs.) or if >72 hrs. not frozen at -70°C or below**
- **Incomplete specimen labeling or documentation, INCORRECT LABELING**
- **Specimens MUST have an accompanying SRD-1 form for each patient**
- **Specimen leaked from container during transit**
- **Insufficient specimen volume for testing**
- **Specimens which do not meet current CDS guidelines for testing (e.g. asymptomatic patients)**
- **Inappropriate specimen type:**
 - **Dry NP swabs not in appropriate transport medium (e.g. VTM)**
 - **Serum**
 - **Specimens not labeled with SPECIFIC source identified (e.g. NP)**

Labeling and Storage

1. Label each specimen with the patient's name, patient's ID number or date of birth and date and time of collection.

Test Request Form

1. Complete an [SRD-1](#) form for each specimen submitted.
2. In the "Test Requested" section under "Other" write "SARS-CoV-2 real time RT PCR". Include the "CDRSS case number" in the box on the top right of the SRD-1 form.
3. Ensure COVID-19 symptoms are filled in the "Pertinent Clinical Information" field on the SRD-1 form.
4. Make sure all physician and clinical laboratory information is completed to avoid delays in reporting.
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 \(2019-nCoV\)](#).

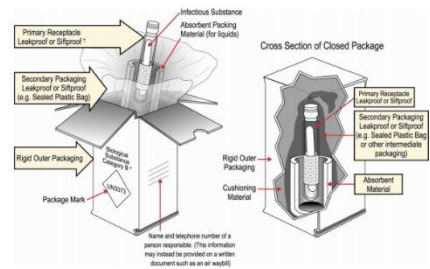
NOTES ON PACKAGING AND SHIPPING CATEGORY B INFECTIOUS SUBSTANCES

[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:

- For information about the CDC laboratory assay : <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>
- Interim Biosafety Guidelines for Handling and Processing Laboratory Specimens (CDC):<https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>
- Interim guidelines for 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>
* On the top left pick “Human” from the “Specimen origin” dropdown menu, Then in the upper right hand section of the form, choose NJ-PHEL from the “Institution name” dropdown menu.
- Link to NJ PHEL SRD-1 Form: <https://www.nj.gov/health/forms/srd-1.pdf>