SARS-CoV-2 Testing for Coronavirus Disease 2019 (COVID-19) Update March 5, 2020

This NJ PHEL Supplemental Technical Bulletin 20.1.3 supersedes NJ PHEL Technical Bulletin 20.1.2 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 have been approved for testing by state public health authorities.** 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 March 11, 2020

- **Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens**

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

- FOR UPPER RESPIRATORY TRACT SAMPLES: PHEL HAS ADOPTED CDC GUIDANCE AND RECOMMENDS THAT NP/OP SAMPLES BE COMBINED AT COLLECTION INTO ONE TUBE LABELED – 'NP/OP'.

  EXCERPT 3/9/2020 INTERIM GUIDELINES FOR COLLECTING SAMPLES:

  "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 2-3 ml of viral transport media".

  COMMERCIAL LABORATORY TESTINGFOR 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: https://www.nj.gov/health/phel/documents/CLIS_Doc/SARS%20CoV-2%20Testing%20PHEL%20Letter%20(new%20link).pdf

Update for March 11, 2020

- **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 and accessioned before 2:30 pm 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 Specimen Arrivals

  Since PHEL is testing on Weekend days, if you have a Person Under Investigation with a CRDSS # and 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 place the box containing the specimens into the double door refrigerator directly on their left. No specimen receiving staff will be available to sign any receipt documents, however this is a secure facility with restricted access and 24/7 video monitoring.

  However, please email the Virology group at Virology.PHEL@doh.nj.gov with the CDRSS# and the estimated delivery time of the specimens "

  - If the specimen box is in the refrigerator Saturday morning before the analyst starts their run, these specimens will be included in the run and the results will be available Sunday morning by approximately 11am.
  - If the specimen box is placed in the refrigerator on Saturday after the analyst starts their run, then these specimens will be included in Sunday's run and the results will be available Monday by approximately 11am.
  - If the specimen box is placed in the refrigerator on Sunday after the analyst starts their run, then these specimens will fall within the weekday specimen receipt guidelines:

  ** Any specimen received, processed, and accessioned by 2:30pm Mon through Fri will be included in that day's run and the results will be available by approximately 11am the next day.*

Update for March 11, 2020

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 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 without a NJDOH approval for testing**
- **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**
- **Specimens MUST have an accompanying SRD-1 form for each patient**
- **Specimen leaked from container during transit**
- **Insufficient specimen volume for testing**
- **Inappropriate specimen type:**
    - **Dry NP/OP swabs not in appropriate transport medium (e.g. VTM)**
    - **Serum**
    - **Specimens not labeled with SPECIFIC source identified (e.g. OP and NP)**

Interim Guidelines for Specimen Collection, Labeling, Storage and Shipping:

Specimen Type and Priority

For initial diagnostic testing for COVID-19, NJDOH recommends collecting and testing upper respiratory (nasopharyngeal AND oropharyngeal swabs), and lower respiratory (BAL if available). Induction of sputum is not recommended. Specimens should be collected as soon as possible, regardless of the time of symptom onset. Maintain proper infection control when collecting specimens.

Specimen collection:

Upper respiratory tract (both recommended)

Nasopharyngeal swab AND oropharyngeal swab (NP and OP swab) 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 a tube containing 2-3 ml of viral transport media.

It is recommended that NP and OP swabs be placed into a single tube, at collection, label the tube "NP/OP" for source of specimen.

***1. Nasopharyngeal swab**:* 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 with the same swab.
***2. Oropharyngeal swab (e.g., throat swab)**:* Swab the posterior pharynx, avoiding the tongue.
Nasopharyngeal wash/aspirate or nasal aspirate. Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

Lower respiratory tract

1. **Bronchoalveolar lavage, tracheal aspirate**. Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

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.
2. Store specimens at 2-8°C for up to 72 hours following collection. If longer storage is required, store at -70°C or lower.

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".
3. Include the "CDS case number" in the box on the top right of the SRD-1 form.
4. Make sure all physician and clinical laboratory information is completed to avoid delays in reporting.

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

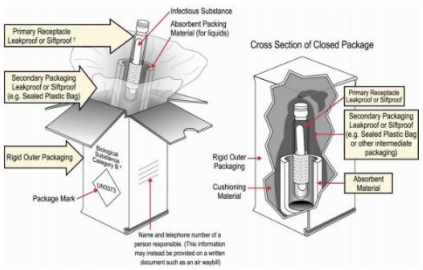
Above is a link to the USDOT packaging instruction for Category B Infectious Substances. The proper shipping name is "Biological Substance, Category B (UN3373)". The proper shipping name and number MUST appear on all paperwork and on the outside of the package. UN diamond shaped certified USDOT hazardous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