SARS-CoV-2 Testing for Persons Under Investigation (PUI) for Coronavirus Disease 2019 (COVID-19) begins at NJ PHEL on February 28, 2020

This NJ PHEL Supplemental Technical Bulletin 20.1.1 supersedes NJ PHEL Technical Bulletin 20.1.0 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 criteria as Persons Under Investigation (PUI) for COVID-19 AND 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

Important Links:

- **To request evaluation of a patient for PUI status:** contact the local health department (LHD) in the jurisdiction where the patient resides: http://www.state.nj.us/health/lh/
- **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 (609)-826-5964 Monday-Friday from 8:00 AM - 5:00 PM.
- **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

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

Specimen Type and Priority

For initial diagnostic testing for COVID-19, CDC recommends collecting and testing upper respiratory (nasopharyngeal AND oropharyngeal swabs), and lower respiratory (sputum, if possible) for those patients with productive coughs. Induction of sputum is not recommended. Specimens should be collected as soon as possible once a PUI is identified, regardless of the time of symptom onset. Maintain proper infection control when collecting specimens.

Specimen collection:

Lower respiratory tract (either, if possible)

1. **Bronchoalveolar lavage, tracheal aspirate**. Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. OR
2. **Sputum**. Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

Upper respiratory tract (both required)

Nasopharyngeal swab AND oropharyngeal swab (NP/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 sterile tubes containing 2-3 ml of viral transport media. NP and OP specimens should be **kept in separate vials and labeled according to their source.**

***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.

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 PUI submitted.
2. In the "Test Requested" section under "Other" write "SARS-CoV-2 real time RT PCR".
3. Include the PUI number in the "CDS case number" 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.

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. Shipping address: **New Jersey Department of Health Public Health and Environmental Laboratories 3 Schwarzkopf Drive Ewing, NJ 08628 ATTN: SPECIMEN RECEIVING**. Specimens may be shipped overnight for delivery on regular business days.
5. For weekend or holiday delivery please consult the laboratory (Tel: (609)-530-8516 or email: Virology.PHEL@doh.nj.gov)

Specimen Rejection criteria

1. Samples without a PUI number OR NJ DOH approval for testing
2. Specimens not kept at 2-8°C (≤72 hrs) or if >72 hrs not frozen at -70°C or below
3. Incomplete specimen labeling or documentation.
4. Inappropriate specimen type
5. Insufficient specimen volume for testing

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).

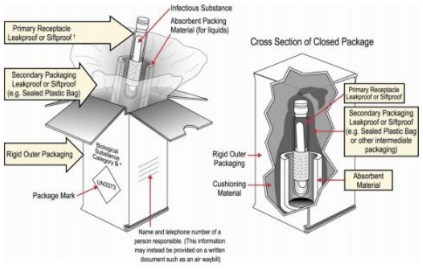
NOTES ON PACKAGING AND SHIPPING CATEGORY B INFECTIOUS SUBSTANCES

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