New Jersey Public Health and Environmental Laboratories
Technical Bulletin 20.1: Novel Coronavirus testing for New Jersey Patients

Technical Bulletin 20.1 (Feb 3 2020): An outbreak of a new (novel) beta coronavirus "2019-nCoV" has been identified in China. The virus can cause an acute respiratory illness. The Centers for Disease Control and Prevention (CDC) reports that "coronaviruses are a large family of RNA viruses that infect many different species of animals, including camels, cattle, cats, and bats. Rarely, animal coronaviruses infect people and then spread between people."

The NJ Public Health and Environmental Laboratory (PHEL) and the NJ Communicable Disease Service (CDS) are working closely with the CDC to monitor the outbreak and prepare testing for this virus. The genetic sequence of the virus from the initial outbreak (identified in a food market in the City of Wuhan, Hubei province) has been shared with the scientific community. The CDC is developing a rapid diagnostic test to distribute to Public Health Laboratories. Over the next few weeks, the CDC will be distributing a real time Polymerase Chain Reaction based assay, for use under an Emergency Use Authorization (EUA).

The CDC is trying to maintain a rapid turn-around time for testing and reporting results from submitted samples. The CDC intends to provide testing kits and a verification panel as part of the EUA process. PHEL will be updating this Bulletin with supplemental information, as is becomes available.

- CDC Situation Summary: https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html
- For more information on n-Cor: https://www.cdc.gov/coronavirus/2019-ncov/about/index.html

Currently all approved samples from Persons Under Investigation (PUI) are being tested by the CDC.

- To request novel coronavirus testing contact the local health department in the jurisdiction where the patient resides. A LHD directory may be found at this link http://www.state.nj.us/health/lh/
- For additional information about the current global distribution of cases, see the CDC Global Map at: https://www.cdc.gov/coronavirus/2019-ncov/locations-confirmed-cases.html#map
- For LABORATORY questions relating to novel coronavirus testing, 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 laboratory information, call: (609)-530-8516 Monday-Friday, 9:00AM to 5:00 PM.
- For CLINICAL guidance, see the NJDOH Communicable Disease Service n-Coronavirus webpage at:

  https://www.nj.gov/health/cd/topics/ncov.shtml or call (609)-826-5964 Monday-Friday from 8:00 AM - 5:00 PM.

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.

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

CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for the 2019 Novel Coronavirus (2019-nCoV) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

Specimen Type and Priority: To increase the likelihood of detecting infection, CDC recommends:

Collection of three specimen types, lower respiratory, upper respiratory and serum specimens for testing is recommended. If possible, additional specimen types (e.g., stool, urine) should be initially collected stored until a decision is made by CDC whether additional specimen sources should be tested. Specimens should be collected as soon as possible once a PUI is identified regardless of symptom onset. Maintain proper infection control when collecting specimens. **Label each specimen with name, patient ID number or date of birth and date and time of collection**.

General Guidelines:

- Store specimens at 2-8°C and ship overnight to CDC on ice pack. Label each specimen container with the patient's ID number (e.g., medical record number), unique specimen ID (e.g., laboratory requisition number), specimen type (e.g., serum) and the date the sample was collected. Complete a CDC Form 50.34 for each specimen submitted. In the upper left box of the form, 1) for *test requested* select "Respiratory virus molecular detection (non-influenza) CDC-10401" and 2) for *At CDC, bring to the attention of* enter "Stephen Lindstrom: 2019-nCoV PUI".

I. Respiratory Specimens:

A. Lower respiratory tract
- Bronchoalveolar lavage, tracheal aspirate. Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C and ship overnight to CDC on ice pack.
- 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. Refrigerate specimen at 2-8°C and ship overnight to CDC on ice pack.

B. Upper respiratory tract

- 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. Refrigerate specimen at 2-8°C and ship overnight to CDC on ice pack.
- *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.
- *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. Refrigerate specimen at 2-8°C and ship overnight to CDC on ice pack.

II. Serum

- Minimum volume required:
  Children and adults: Collect 1 tube (5-10 mL) of whole blood in a serum separator tube.
  Infant: A minimum of 1 mL of whole blood needed for testing pediatric patients. If possible, collect 1 mL in a serum separator tube.
- Serum separator tubes should be stored upright for at least 30 minutes, and then centrifuged at 1000–1300 relative centrifugal force (RCF) for 10 minutes before removing the serum and placing it in a separate sterile tube for shipping (such as a cryovial). Refrigerate the serum specimen at 2-8°C and ship overnight to CDC on ice-pack.

III. Shipping

Specimens PUI's must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations external icon. Store specimens at 2-8°C and ship overnight to CDC on ice pack. If a specimen is frozen at -70°C ship overnight to CDC on dry ice. 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).

For additional information, consultation, and the CDC shipping address, contact the CDC Emergency Operations Center (EOC) at 770-488-7100.

IATA/USDOT CATEGORY B SHIPPING AND PACKAGING INSTRUCTIONS:

https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&ty=HTML&h=L&mc=true&=PART&n=pt49.1.173#se49.2.173_1199

Above is a link to the USDOT Biological Substance, Category B UN 3373 packaging instructions. Category B is an Infectious Substance. 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 ALL packaging instructions. If a shipper ships both Category A and B, then 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: 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 then 1L. The outer packaging must not contain more than 4 L.

    c. **The primary container or secondary packaging must be able to withstand changes an internal 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).**

SUMMARY:

Specimen Rejection criteria:

- Specimens not kept at 2-8°C (≤4 days) or frozen at -70°C or below.
- Incomplete specimen labeling or documentation.
- Inappropriate specimen type.
- Insufficient specimen volume.

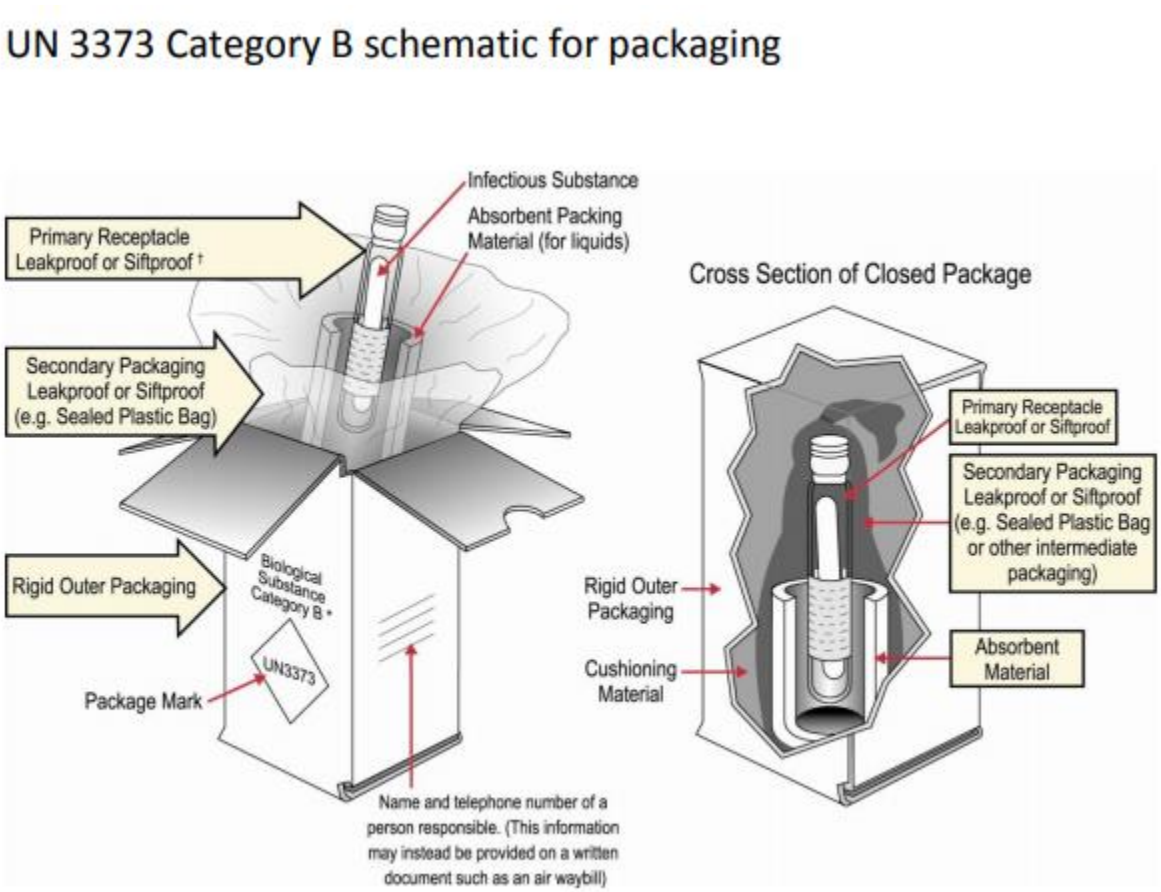
Most Common Problems that may delay reporting:

- Patient name on the test request form does not match patient name on the specimen.
- Incomplete clinical information
- Incorrect FAX numbers for receiving results
- Failure to provide times and dates when sample was collected

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

Real time RT-PCR assay parameters suggest that the specimen be analyzed within 72 hours if stored at 2-8 º C.

In the event the specimen cannot be shipped and/or received overnight at the testing laboratory (CDC), freeze at –70 º C and ship on dry ice. Special arrangements for shipping to CDC should be arranged with CDS and CDC.



- Use appropriate cold packs for shipping.

<u>If it is necessary to use dry ice Overpack label</u>:

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