Collecting and Handling Laboratory Specimens from Nebraska Patients with Suspected COVID-19

Introduction
Healthcare Personnel (HCPs) who collect, handle, transport or test clinical specimens from a patient under investigation (PUI) for Coronavirus Infectious Disease-19 (COVID-19) with the SARS-CoV-2 virus should adhere rigorously to the following precaution measures and biosafety practices listed in https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html. HCPs caring for patients with COVID-19 are at elevated risk of exposure.

HCPs should be prepared to:
✓ Identify patients in accordance to the CDC Case definition: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html
✓ Isolate patients by placing a facemask on the patient and isolate in an examination room with the door closed. It is recommended patients be isolated in an Airborne Infection Isolation Room (AIIR) or if not available, placed in a room where the exhaust is not recirculated within the building without HEPA filtration.
✓ Inform both in-house infection prevention (IP) personnel and the local health department (LHD). (http://www.dhhs.ne.gov/Pages/LHD)
✓ Initiate collection of specimens using appropriate Personal Protective Equipment (PPE) for respiratory pathogens.

Testing at Nebraska Public Health Laboratory
STREAMLINED COVID-19 TEST ORDERING AT NEBRASKA PUBLIC HEALTH LAB (NPHL) FOR SELECT PATIENTS
We are enabling direct on-line ordering of the COVID-19 PCR test at NPHL without telephone pre-approval or PUI number given by public health. Patients tested at NPHL are REQUIRED to meet the priority requirements below:

In-patients: Any in-patient will be tested.
Out-patients: Persons in these groups with a clinical diagnosis of COVID-19 can be tested at NPHL.
- Healthcare workers
- Public Safety/First Responders (EMS, law enforcement, firefighters)
- Residents and staff at nursing homes
- Residents and staff at group homes, homeless shelters, and daycare facilities
- Individuals > 65 years old, and anyone with underlying conditions

Providers can seek NPHL testing for patients who fail to meet these requirements based on special circumstances that warrant rapid turnaround time. Contact a state/local public health authority for telephone pre-authorization. For all other patients, order COVID-19 testing through the commercial laboratories.

On-line ordering of the COVID-19 test should be completed using the NUlirt online ordering system at NPHL. Laboratories MUST work with ordering physicians who send specimens to onsite lab to be entered into NUlirt. Written COVID-19 orders MUST accompany patient specimen, including demographics and all criteria above. Specimen should NOT be accepted unless written orders are included with the specimen, as per routine laboratory requirements. Laboratories are NOT allowed to falsify criteria if unknown, per CLIA regulations1. Access NUlirt through this link https://nulirt.nebraskamed.com using your existing NUlirt account. If you are a new user, follow the link to register and create a new account. See instructions below.

There are options (below) for ordering a test at NPHL. While the preference is to use on-line NUlirt (the NPHL lab information system) ordering to complete an order (options 1, 2, and 3), the fourth option below provides for paper requisition/ submission to NPHL where the order will be entered into NUlirt at the time of receipt at NPHL. When ordering electronically through NUlirt, pay particular attention to the e-mail account (i.e., user id) utilized at the time of log-on to NUlirt, as the result will be reported back by secure e-mail to that account. Collect the patient specimen either in-clinic or at a designated COVID-19 collection site. Those ordering electronically need to generate a printed, completed NPHL order by clicking the NUlirt system to accompany the specimen.
1) Ordering providers can utilize existing account or set up a new account, to order COVID-19 tests directly on-site. This entails collecting the specimen, labeling the specimen, submitting the order into NUlirt, printing out the “completed order” and “batch shipping” documents from NUlirt, and arranging for courier delivery of specimens and associated documents via NPHL client services (402-559-2440).

2) Laboratories can place the order into NUlirt on behalf of an ordering provider. Providers must submit the specimen accompanied by a completed COVID-19 NPHL REQUISITION (attached) to the laboratory placing the order into NUlirt. Laboratories cannot place the order into NUlirt without the signed COVID-19 NPHL REQUISITION. Ordering laboratories are responsible for getting test results back to the ordering provider.

3) Ordering providers can refer patients to designated COVID-19 specimen collection sites, and fax or e-mail a completed COVID-19 NPHL REQUISITION OR have the patient take the completed form with them to the specimen collection site. COVID-19 specimen collection sites must have a completed, signed COVID-19 NPHL REQUISITION to proceed with specimen collection if referring the specimen to NPHL. COVID-19 specimen collection sites can place the order electronically into NUlirt, or reflex to option #4. Specimen collection sites placing electronic orders are responsible for getting test results back to the ordering provider.

4) Ordering providers, laboratories, and designated COVID-19 specimen collection sites can send the COVID-19 NPHL REQUISITION PLUS the NP specimen via courier to NPHL where the test will be electronically ordered through NUlirt. Please note the importance of specifying the account on the COVID-19 NPHL REQUISITION to insure delivery of the test result via fax or secure e-mail.

NUlirt Entry Instructions
Access NUlirt here (https://nulirt.nebraskamed.com) using your existing NUlirt account. If you are a new user, follow the link to register and create a new account. If you are having issues getting access to NUlirt, reach out to the NUlirt support group via email nulirtsupport@nebraskamed.com. There are also client service representatives available to assist with ordering through the NUlirt system at 402-559-2440; or toll free: 1-866-290-1406.
These recommendations are subject to revision depending on COVID-19 lab testing capacity at NPHL and commercial laboratories.

New members can set up only one (1) email addresses but will receive notification when results are available. Report can be shared with ordering physician or lab for reporting.

Complete patient information. This is required for reporting to public health.

Click RED ORDER button to begin.
COVID-19 Outbreak Order

Please, for this test to be completed at NPHL you must answer these questions accurately and completely. ALL patients tested for COVID-19 should be isolated (whether at home or in the hospital) pending test results. The result will return to you (the ordering provider) via secure email and you should communicate the result to the patient.

Most outpatients with a clinical presentation consistent with COVID-19, after ruling out alternative diagnoses (negative RPP), should be considered a probable case of COVID-19 and self-isolate without expecting testing.

Outpatients that are members of vulnerable or high risk populations with a clinical presentation consistent with COVID-19, after ruling out alternative diagnoses (negative RPP), should be considered for testing.

Inpatients with a clinical presentation consistent with COVID-19, after ruling out alternative diagnoses (negative RPP), should be considered for testing.

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Click arrow to choose if your facility is listed
Click on “What’s This? to define

Complete information and click REVIEW and SUBMIT ORDER

Print both “patient details” and “order inventory form” to send with the specimen. These are a laboratory requirement to perform the test.
Testing at Commercial Laboratories

Commercial laboratories have come on board nationally to test for COVID-19. Physicians should consider if a lab test is warranted, assess whether clinical diagnosis of COVID-19 infection suffices, or if laboratory diagnosis is even necessary. Patients with a clear source of exposure (e.g., household member of a known lab-confirmed case) and a clinical presentation consistent with COVID-19 are now a lower priority for testing. Prioritize limited laboratory testing capacity for patients with the highest pre-test probability (the most severely ill who fit COVID-19 profile) and lacking a clearly identifiable source/exposure and flu/RPP tests negative.

Generally, most facilities have an established relationship with a commercial laboratory. If not already established, the facility should set up a commercial account to arrange computer access and courier pickup. Standard patient collection centers and other phlebotomy sites provided by commercial labs traditionally cannot collect specimens.

Commercial laboratories currently experience the same bottlenecks with delayed results. Further details can be found at the commercial laboratory’s website or contact them directly.

Respiratory Specimen Collection

Maintain proper infection control (https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html#a4) when collecting specimens or performing other aerosolizing procedures. Use appropriate PPE-following standard, contact, airborne precautions plus eye protection such as goggles and/or disposable face shield, respirator-preferably N-95, N-99 or Powered Air Purifying Respirator (PAPR), a long-sleeved gown, and gloves. The surgical mask can be used when triaging the patient, however CDC recommends the respirator when possible to collect actual specimen due to the risk of aerosolization.

A video on PPE donning and doffing is available at: https://www.youtube.com/watch?v=bG6zISnenPg
A video for NP swab collection is available at: https://www.youtube.com/watch?v=hXohAo1d6tk

Collect one (1) Nasopharyngeal (NP) swab. NOTE: The oropharyngeal swab (OP) has been discontinued. Facilities must first perform a risk assessment to assess if collection or testing can be safely performed. If a facility is unable to safely collect or perform multiplex PCR, see notes below. Specimens should be collected as soon as possible once a PUI is identified to fit the CDC criteria regardless of the time of symptom onset.

Nasopharyngeal

✓ Only one NP swab is required as long as the viral transport medial (VTM) vial contains 2-3mL of media to perform both the multiplex Respiratory Pathogen Panel (RPP) and the COVID-19 NPHL test if requested.
✓ Collect additional NP swabs (2 swabs) if:
  • Vial contains <1mL transport media. Normal saline or PBS is acceptable if viral transport is not available.
  • Additional testing is sent to commercial laboratories outside of Nebraska or
  • Rapid detection tests require extracting reagent be added to the original specimen.
✓ Use only swabs designed for NP collection, usually a mini-tipped synthetic fiber swab with thin plastic shaft. Acceptable collection devices are VTM, UTM, VCM or M4. Do not use calcium alginate swabs or swabs with wooden shafts used for bacterial cultures, as they may contain substances that inactivate some viruses and inhibit PCR testing.
✓ HCP should stand to the side, not directly in front of the patient when collecting to avoid aerosols.
✓ Insert a swab into the nostril parallel to the palate. Do not sample the nostrils or tonsils.
✓ Gently hold, then rotate swab to absorb secretions.
✓ Slowly withdraw the swab.
✓ Place swab immediately into a sterile tube containing 2-3 ml of VTM.
✓ Aseptically cut swab stick off to permit tightening of the cap. If the swab has a break line, cover vial opening with gauze and hold away from HCPs and patients, to break off swab handle.
✓ Tighten cap on vial, make sure shaft of swab is short enough not to be in contact with lid, thus preventing a secure seal and leakage in transport.
✓ Confirm labels with patient ID.
✓ Label specimen container (i.e., primary container) Label must contain patients first and last name, date of birth, time and date of collection, source and collector initials.
✓ Ideally refrigerate specimen at 2-8°C immediately after collection.
Instruct couriers to transport on ice or frozen gel packs. Courier arrangements are addressed below. If courier or FedEx arrangements cannot be made within 72 hours, the specimen should be frozen at -20°C, and shipped on Dry Ice. Write “Frozen Specimen” on the NUlirt batch list or the NPHL Test Request form.

Specimens can be kept frozen at -20°C for up to 30 days.

Lower Respiratory

The induction of sputum is not recommended. However, patients for whom it is clinically indicated (e.g., those receiving invasive mechanical ventilation), a lower respiratory tract aspirate or bronchoalveolar lavage sample can be collected and tested in-house for bacterial or fungal pathogens.

Consult infectious diseases/infection control if other specimen types such as sputum can be safely collected for in-house testing. Sputum can be obtained if PUI has a productive cough and can produce sputum.

If the specimen is collected using an aerosol-generating procedure (such as tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation or bronchoscopy), the PUI should ideally be in an AIIR. If this is not possible than they should be placed in a private room with the door closed. The exhaust from this room should not recirculate throughout the facility without HEPA filtration.

Patient should rinse their mouth with water, then expectorate deep cough sputum directly into a sterile, leak-proof screw-cap collection cup or a sterile dry container.

Only the PUI and essential HCP should be in the room wearing appropriate PPE.

Lower respiratory specimens ordered for bacterial or fungal culture should be forwarded to the in-house laboratory. Specimen containers and reference laboratory order forms should be clearly labeled with “PUI for COVID-19.”

Rapid Respiratory Panel (RPP) To Rule-Out Other Pathogens

Respiratory pathogen panel (RPP) and influenza testing are less important and no longer required as part of the algorithm for COVID-19 workup and testing. However, in situations where testing capacity is limited, using RPP as a triage test and performing COVID-19 testing only if negative remains a useful strategy to preserve testing capacity.

Packing, Shipping and Transport to NPHL

Packaging, shipping, and transport of PUI specimens to NPHL must follow shipping regulations for UN 3373 Biological Substance, Category B. All personnel who package and transport specimens (including couriers) need to be trained in safe handling practices and spill decontamination procedures.

Laboratories should be proactive and calculate the most efficient means of transporting specimens to NPHL, prior to the arrival of the first suspected PUI. Call NPHL Client Services at (866) 290-1406 to ask what the ground options are for your location. Client Services hours are 24/5 Monday-Friday, and Saturday/Sunday from 7am to 3pm. To make arrangements after 3pm on Saturday or Sunday, call the client services pager at 402-888-2086. If distance is problematic or if ground shipping is not sufficient, consider shipping by FedEx in an insulated Category B shipper using FedEx Priority shipping (NOT Overnight) for delivery by 10:30am to NPHL client services.

Place each specimen in leak-proof specimen bag (i.e., secondary container) with absorbent material. Seal.

DO NOT use a pneumatic-tube system to transport these specimens in-house.

Ideally, specimens should be immediately refrigerate at 2-8°C upon collection. Keep refrigerated at all times, including transport.

If frozen before shipment, transport on dry ice and document “Frozen Specimens” in NUlirt batch list.

COVID-19 test code in NPHL’s NUlirt Order Entry system is available, with complete documentation of patient demographics. Facilities are encouraged to sign-up on https://nulirt.nebraskamed.com. Orders placed through NUlirt can print as a batch list.

Place NPHL batch list or requisition in the outside pocket of the specimen bag.

Specimens sealed in secondary biohazard bags with appropriate paperwork, can be given directly to a routinely scheduled NPHL ground courier. No special ambient Category B boxes are required unless shipping by FedEx. For FedEx shipping, a box marked UN3373 with Styrofoam and gel pack is required.

If NPHL couriers are not routinely scheduled, specimens should be arranged by calling Client Services support. Main Line: (402) 559-2440, Toll-Free: (866) 290-1406 or Client Service Pager: (402) 888-2086.

If NPHL ground courier is unable to transport to NPHL within a reasonable time, please call the NPHL emergency pager at (402) 888-5588 to arrange FedEx shipments.

All couriers must transport to: Nebraska Public Health Lab, 4400 Emile Street MSB 3500, Omaha 68105
In-House Clinical Laboratory Testing
When indicated, clinical laboratories should continue to perform routine hematology, urinalysis, and clinical chemistry studies. Microbiology lab can perform diagnostic tests on blood, sputum, urine, or stool specimens.

Facilities must first perform a Risk Assessment to identify the tasks that create aerosols (below) and mitigate prior to testing in a clinical settings, also known as biosafety level-2 (BSL-2). One method of mitigation is to enhance biosafety precautions by implementing enhanced BSL-3 practices. Ideal BSL-3 practices include wearing respiratory protection (such as a fit-tested N-95 or N-99 respirator or surgical mask if N-95 not available although this is not as protective), a face shield or goggles, and work in a Biological Safety Cabinet (BSC). To use the BSC, work slowly and methodically, from dirty to clean, and remove gloves immediately after every exit. See BSC just-in-time training at: https://www.youtube.com/watch?v=96-aZLom340

Not all enhancements may be possible, but all conceivable measures must be taken to protect the HCP. The following activities that involve manipulation of potentially infected respiratory specimens should be performed in a certified Class II BSC:

- Performing rapid diagnostic test kits such as those used for RSV, Strep A, and influenza kits (all respiratory specimens testing should be manipulated inside the BSC).
- Adding specimen aliquots to test analyzers e.g. multiplex PCR cartridges.
- Aliquoting, vortexing and/or diluting specimens.
- Inoculating bacterial or mycological culture media.
- Nucleic acid extraction procedures.
- Preparation and chemical- or heat-fixing of smears for microscopic analysis.
- Opening of sealed rotor centrifuge cups or centrifuged specimen containers in unsealed rotor cups.

BSC NOTE: Remove gloves upon every exit of the cabinet, use good glove-glove technic, move slowly not to aerosolize what has contaminated the gloves.

Facilities performing the following activities causing aerosolization but are unable to use a BSC must consider enhancing precaution when working on the bench. Upon performing a risk assessment consider using face shield or goggles and N95 or N-99 (or surgical mask if N95 are not available or in short supply although this is not as protective), and performed behind a Plexiglass tabletop splashguard if possible:

- Performing any rapid diagnostic test kit such as those used for RSV, Strep A, or influenza kits in a laboratory, clinic settings or doctor’s office where a BSC is not available.
- Vortexing stools or other specimens without caps on an open bench top
- Loading and unloading of automated tests e.g. multiplex PCR panel
- Working with multi-plex instruments when kits or panels lodge, are stuck or broken and require additional manipulation
- Laboratorian is immunosuppressed or has a co-morbidity

Notes:
- If a facility is unable to safely collect specimens, notify the LHD for directions to alternate collection locations.
- Questions to NPHL should go through nphl@unmc.edu.
- If a laboratory test confirms the presence of another respiratory pathogen such as the influenza virus, RSV, or *Streptococcus pneumonia*, but clinical suspicion remains high for either a co-infection or a secondary infection, then consideration for testing for the virus causing COVID-19 should be discussed with public health officials.
- Laboratory waste can be handled as all other medical waste. Use two red liner bags, tie with an overhand balloon knot, place waste and sharps waste inside double bags. Contact medical waste courier for specific requirements.
- BioFire Diagnostics has reported that the coronavirus targets on their panels do not cross-react with the COVID-19 disease virus.

i https://oig.hhs.gov/authorities/docs/cpglab.pdf

https://emergency.cdc.gov/han/2020/HAN00430.asp Updated March 17, 2020
http://dhhs.ne.gov/News/News-Releases.aspx
https://www.biofiredx.com