University of Nebraska Medical Center
REGIONAL PATHOLOGY SERVICES

LAB ALERT: Collecting and Handling Laboratory Specimens from Nebraska Patients with Suspected COVID-19 Infection

Date: March 6, 2020

Dear Regional Pathology Services Clients,
Below is guidance released today by The Nebraska Public Health Laboratory (NPHL) regarding the collection, handling and transport of specimens from patients suspected of having the COVID-19 infection. UNMC and Nebraska Medicine are currently working on a laboratory assay that may be used for the detection of COVID-19 that will become available within the next few weeks. Currently, any testing for COVID-19 needs to be approved through your local health department (LHD). Specimens will be tested and resulted within 48 hours at NPHL. A list of all LHD's can be found at http://www.dhhs.ne.gov/Pages/LHD. Please note that this information changes daily, we will inform clients of any updates as they become available.

Healthcare Personnel:

Healthcare Personnel (HCPs) who collect, handle, transport or test any clinical specimens from a patient under investigation (PUI) for Coronavirus Disease COVID-19 with 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 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)
- **Both must be called before specimens are collected. Testing at NPHL will need prior approval. Questions to NPHL should go through nphl@unmc.edu .**
- Initiate collection of specimens use appropriate Personal Protective Equipment (PPE) for respiratory pathogens.

Respiratory Specimen Collection:

Maintain proper infection control (https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html#a4) when collecting specimens. Use appropriate PPE-following standard, contact, airborne precautions and eye protection i.e., eye protection such as goggles and/or disposable face shield, respirator-preferably N-95s or Powered Air Purifying Respirator (PAPR), a long-sleeved gown, and gloves. A video on PPE donning and doffing is available here:

https://www.youtube.com/watch?v=bG6zISnenPg

Once testing for the virus at NPHL has been approved, collect one (1) Nasopharyngeal (NP) swab. NOTE: The oropharyngeal swab (OP) has been discontinued. On-site respiratory multiplex PCR analysis is recommended only if the facility's laboratory has performed a risk assessment and can safely perform the test. If a facility is unable to safely perform multiplex PCR, see notes below. Specimens should be collected as soon as possible once a PUI is identified (and approval given), regardless of the time of symptom onset. For HCP, testing may be considered if

there has been exposure to a PUI without laboratory confirmation.

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 in-house multiplex Respiratory Pathogen Panel (Test code: RESPP) and the COVID-19 NPHL test. Otherwise, collect an additional NP swab to assure there is sufficient media. (Testing of the panel would be performed at the on-site laboratory first, then sent to NPHL).
- Use only swabs designed for NP collection, usually a synthetic fiber swab with plastic shaft. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. Kits containing both swabs and viral transport media (VTM, UTM, VCM or M4) can be obtained from the LHD after approval has been granted.
- Nasopharyngeal swab: 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. Gently hold, then rotate swab to absorb secretions. Slowly withdraw the swab. Do not sample the nostrils or tonsils.
- 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 and parafilm or tape around the top to secure cap.
- Place patient's label on the specimen container (i.e., primary container) after collection only after name has been confirmed with patient ID. Label must contain patients first and last name, date of birth, time and date of collection, source and collector initials.

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 patient can produce sputum, have the patient rinse their mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof screw-cap collection cup or a sterile dry container.
- 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.
- During specimen collection only the PUI and essential HCP should be in the room.
- If required, lower respiratory tract specimens ordered for bacterial or fungal culture should be forwarded to the on-site laboratory. If specimens are routinely forwarded to an off-site reference laboratory, first contact the reference laboratory for acceptability. Specimen containers and reference laboratory order form should be clearly labeled with "PUI for COVID-19."

Packing, Shipping and Transport:

Packaging, shipping, and transport of specimens from a PUI 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 (800) 290-1406** to ask what the ground options are for your location. Consider shipping by FedEx using priority for delivery by 10:30am to NPHL client services, if ground not sufficient.

- Place each specimen in leak-proof specimen bag (i.e., secondary container). Seal.
- DO NOT use a pneumatic-tube system to transport these specimens in-house.

- Refrigerate specimen at 2-8°C before and during transport with frozen gel packs.
- Legibly complete entire NPHL Test Request Form http://nphl.org/forms.cfm, including correct patient address. Check line with "COVID-19" test order found under the Molecular Virology section of the new NPHL Test Request form on our website listed above. Older forms do not include this test order, therefore write "COVID-19" in the "Comments" section.
- Write "PUI for COVID-19" on the top of all forms and document name of NeDHHS staff to approve testing.
- Place NPHL Form in separate pocket on outside of specimen bag.
- Refrigerate specimen until NPHL ground courier arrives.
- 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.
- Non-STAT specimens by ground can be transported by a routinely daily scheduled NPHL or other in-state reference lab courier without calling for arrangements.
- When NPHL couriers are not scheduled routinely, Non-STAT specimens should be arranged by calling NPHL Client Services support. Main Line: (402) 559-2440, Toll-Free: (866) 290-1406 or Client Service Pager: (402) 888-2086.
- If STAT or a NPHL ground courier is unable to transport to NPHL within the day, please call the NPHL emergency pager at (402) 888-5588 to arrange FedEx shipments.
- The Local Health Department will complete the PUI and Case Report form and email to NPHL at
- nphl@unmc.edu or fax to (402) 559-7799.
- All request for results must go through the local health departments.

Clinical Laboratory Testing On-Site:

When indicated, clinical laboratories should continue to perform routine hematology, urinalysis, and clinical chemistry studies. Microbiology laboratories 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 respirator or surgical mask if N-95 not available), 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 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 doing risk assessment, consider using face shield or goggles and N95 (or surgical masks if N95 are not available or in short supply), and performed behind a Plexiglass splash guard 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 BSC is not available.
- Vortexing stools or other specimens without caps on open bench top
- Loading and unloading of automated tests e.g. multiplex PCR cartridges
- Working with multi-plex instruments when kits or cartridges lodge or are stuck or broken and require additional manipulation
- Laboratorian is immunosuppressed or have a co-morbidity

Notes:
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 disease 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. If the PCR assay is negative for all targets, call your local health department for advice on whether to forward the respiratory specimen to NPHL.

If your facility is unable to safely perform multiplex PCR analysis utilizing BSL-3 practices, the specimen can be submitted to Regional Pathology Services for PCR analysis. Please write possible COVID-19 PUI" on top and check "Respiratory Pathogen Panel" on the Regional Pathology Services (RPS) Clinical Test Request Form found at

http://www.reglab.org/reglab/assets/File/Green%20Clinical%20Req%20Fillable.pdf

Nebraska Public Health Laboratory Testing:

The FDA announced the release of the Emergency Use Authorization (EUA) of CDC's 2019 Coronavirus (COVID-19) Disease Real-time RT-PCR Diagnostic Panel to select public health laboratories. Nebraska Public Health Laboratory has this screening test in-house, validated and is available to test a Nebraska PUI when approved by LHD or the State. Specimens will be tested and resulted within 48 hours. STAT courier services and testing will depend on the nature of the PUI and must be cleared by NeDHHS. NPHL aspirates to ensure that turn-around time and reporting of positive and negative results meet the needs of our HPCs.
Other resources:

Additional Resources:

Recommendations for Reporting, Testing, and Specimen Collection Updated February 28, 2020;

https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html,

Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) Updated March 1;

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

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance

https://emergency.cdc.gov/han/2020/HAN00428.asp

https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html

https://www.biofiredx.com

If you have any questions or issues with these changes please contact client services at 402-559-6420 and ask to speak with one of the client coordinators.