February 28, 2020 (replaces version dated February 3, 2020)

To: All North Carolina Clinicians and Laboratories
From: Zack Moore, MD, MPH, State Epidemiologist
      Scott Shone, PhD, HCLD (ABB), Laboratory Director
Re: Coronavirus Disease 2019 (COVID-19)

This memo is intended to provide the latest information to all North Carolina clinicians and laboratory staff regarding the Coronavirus Disease 2019 (COVID-19). This version includes the following updates:

- Updated criteria to guide evaluation for patients under investigation for COVID-19, and
- Updated specimen collection and laboratory testing guidance for suspected cases of COVID-19.

Summary

This is a rapidly evolving situation. The most up to date information and guidance can be found at https://www.cdc.gov/coronavirus/2019-ncov/index.html and https://epi.dph.ncdhhs.gov/cd/diseases/2019nCoV.html.

Case Investigation and Testing
- Clinicians are encouraged to screen for possible infection by the virus that causes COVID-19 by asking:
  - Does the person have fever\(^1\) OR symptoms of lower respiratory illness, such as cough or shortness of breath?
    \[\text{AND}\]
  - Has the patient traveled to an affected geographic area\(^2\) within 14 days of symptom onset?
    \[\text{OR}\]
  - Has the patient had close contact\(^3\) with a person with COVID-19?

- Patients who meet the following criteria should be evaluated as a Patient Under Investigation (PUI) in association with the outbreak of COVID-19:
  - Fever\(^4\) OR signs/symptoms of lower respiratory illness (e.g., cough, shortness of breath) in any person, including healthcare workers\(^4\), who has had close contact\(^3\) with a laboratory-confirmed\(^5\) COVID-19 patient within 14 of symptom onset.
- Fever AND signs/symptoms of lower respiratory illness (e.g., cough, shortness of breath) requiring hospitalization in any person with history of travel from affected geographic areas within 14 days of symptom onset.

- Fever with severe acute lower respiratory illness (e.g., pneumonia, ARDS) requiring hospitalization and without alternative explanatory diagnosis (e.g., influenza) in a person where no source of exposure has been identified.

**Reporting**

- Effective February 3, 2020, physicians and laboratories in North Carolina are required to immediately report when novel coronavirus infection is reasonably suspected to exist.

- Clinicians caring for patients with possible COVID-19 should immediately contact their local health department or the state Communicable Disease Branch (919-733-3419; available 24/7) to review the risk assessment and discuss laboratory testing and control measures.

- Clinicians should also contact local or state public health if COVID-19 is suspected even if the above PUI criteria are not met.

- Persons in whom COVID-19 infection is suspected should also be evaluated for common causes of community-acquired respiratory illness, if not already done. (Note: For biosafety reasons, viral culture should not be attempted in cases meeting the PUI criteria.) The state or local health department should still be consulted if the patient tests positive for another respiratory pathogen as information is limited on the likelihood of coinfections in patients with COVID-19.

- Any cluster of severe acute respiratory illness in healthcare workers in the United States should prompt immediate notification of local or state public health for further investigation and testing.

**Infection Control**

- CDC currently recommends a cautious approach to management of known or suspected cases.
  - Standard, contact, and airborne precautions are recommended for management of patients in healthcare settings with known or suspected COVID-19. These include:
    - Use of fit-tested NIOSH-approved N95 or higher level respirators
    - Use of gowns, gloves and eye protection (e.g., goggles or face shield)
    - Use of negative-pressure airborne infection isolation rooms if available
  - Patients should be asked to wear a surgical mask as soon as they are identified as having symptoms of respiratory illness
  - Isolate patients in a private room with the door closed (use an airborne isolation room, if possible).
  - Patients with known or suspected COVID-19 should continue to wear a mask if placed in a private, non-airborne isolation room or if they must be moved from their room.

- As the situation continues to evolve, please find updated guidance at https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html.

**Treatment**

- No vaccine or specific treatment for COVID-19 is available; care is supportive.
- Corticosteroids should be avoided unless indicated for other reasons (for example, chronic obstructive pulmonary disease exacerbation or septic shock).
Testing
- Testing is available at the CDC through the NC State Laboratory of Public Health (NCSLPH). The NCSLPH is currently completing a verification process of the CDC’s 2019-nCoV Real-Time RT-PCR Diagnostic Panel for in-state testing. THIS GUIDANCE MEMO WILL BE UPDATED WHEN THAT TESTING BECOMES AVAILABLE.

- Prior approval from the State Communicable Disease Branch (919-733-3419; available 24/7) is required. CONTACT THE BIOTERRORISM AND EMERGING PATHOGENS UNIT’S DUTY PHONE (919-807-8600) PRIOR TO ANY SHIPMENT OR IF YOU HAVE QUESTIONS.

- Specimens should be collected and packaged on ice as UN3373 Category B for pickup by DASH or other prearranged courier as soon as possible once a PUI is identified regardless of time of symptom onset. Additional guidance for collection, handling, and testing of clinical specimens is available at https://slph.ncpublichealth.com/bioterrorism/2019-ncov.asp and https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html/.

- To increase the likelihood of detecting an infection, CDC recommends collecting and testing multiple clinical specimens from different sites, including upper respiratory (nasopharyngeal and oropharyngeal swabs) and lower respiratory specimens (sputum, if possible).
  - Upper respiratory tract
    - Nasopharyngeal AND oropharyngeal swabs (NP/OP swabs)
      - Use only synthetic fiber swabs with plastic or metal 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 swabs should be placed and kept in separate vials. Refrigerate specimen at 2-8°C and coordinate prompt shipping to NCSLPH through the BTEP duty phone.
      - Nasopharyngeal swab: Insert a swab into the nostril parallel to the palate until resistance is encountered. Gently rub and roll the swab, leaving in place for a few seconds to absorb secretions before removing. Swab both nasopharyngeal areas with the same swab.
      - Oropharyngeal swab (e.g., throat swab): Swab the posterior pharynx and tonsillar areas. Rub swab avoiding contact with tongue, teeth, and gums.
  - Lower respiratory tract
    - Sputum if possible when a productive cough is present. Sputum should not be induced.
      - 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 coordinate prompt shipping to NCSLPH through the BTEP duty phone.

- All specimen submissions must have a completed NCSLPH BTEP Specimen Submission Form and an Interim CDC Patient Under Investigation form.

- This is a novel emerging coronavirus and the performance characteristics to detect COVID-19 using current assays that target human coronavirus, SARS, or MERS are not established. Therefore, it is important that local or state public health officials be notified of PUI, so that arrangements can be made for testing at CDC where a qualified assay is currently available. All submissions to CDC MUST be routed through NCSLPH.

- For more information and updated information, please see NCSLPH 2019-nCoV Clinical Laboratory Guidelines.
Notes:
1 Fever may be subjective or confirmed. Fever may not be present in some patients, such as those who are very young, elderly, immunosuppressed, or taking certain fever-lowering medications. Clinical judgment should be used to guide testing of patients in such situations.
2 Affected areas are defined as geographic regions where sustained community transmission has been identified. Relevant affected areas will be defined as a country with at least a CDC Level 2 Travel Health Notice. See all COVID-19 Travel Health Notices.
3 Close contact is defined as:
   a) being within approximately 6 feet (2 meters), of a COVID-19 case for a prolonged period of time while not wearing recommended personal protective equipment or PPE (e.g., gowns, gloves, NIOSH-certified disposable N95 respirator, eye protection); close contact can include caring for, living with, visiting, or sharing a healthcare waiting area or room with a COVID-19 case.
   – or –
   b) having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on) while not wearing recommended personal protective equipment.
4 For healthcare personnel, testing may be considered if there has been exposure to a person with suspected COVID-19 without laboratory confirmation
5 Documentation of laboratory-confirmation of COVID-19 may not be possible for travelers or persons caring for COVID-19 patients in other countries.
6 Category includes single or clusters of patients with severe acute lower respiratory (e.g., pneumonia, ARDS) of unknown etiology in which COVID-19 is being considered.