FAX

TO:	Dare County Healthcare Providers	FROM:	Department of Health & Human Services
PAGES: INCLUDES COVER	6	PHONE:	252.475.5003
SUBJECT:	Coronavirus Disease	DATE:	March 4, 2020

Dear Colleagues,

Attached is an updated memo on Coronavirus Disease. North Carolina has completed verification of the CDC 2019-nCoV real-time RT-PCR Diagnostic Panel.

As a reminder, Dare County Public Health does not provide primary care, therefore, we do not offer testing at this time. Primary care providers are encouraged to screen for possible infection, report to NC Communicable Disease and Dare County Public Health and test per State Lab of Public Health guidance.

Dare County Public Health staff can be reached after hours at 252.473.3444.

Thanks

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NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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ELIZABETH CUERVO TILSON, MD, MPH • State Health Director
MARK T. BENTON • Assistant Secretary for Public Health
Division of Public Health

March 2, 2020 (*replaces version dated February 28, 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 (5 pages)

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:

- Substantial changes have been made to incorporate new laboratory testing information throughout pages 3 - 5.

Summary
A respiratory disease named "coronavirus disease 2019" (abbreviated "COVID-19") caused by a novel coronavirus named "SARS-CoV-2" was first detected in China in late 2019 and has subsequently spread to many other countries, including the United States. WHO announced a Public Health Emergency of International Concern on January 30 and the U.S. Department of Health and Human Services declared a public health emergency on January 31, 2020.

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?
    AND
  - Has the patient traveled to an affected geographic area[2] within 14 days of symptom onset?
    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[1] 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-19patient within 14 of symptom onset.

- Fever[1] 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[2] within 14 days of symptom onset.

- Fever[1] with severe acute lower respiratory illness (e.g., pneumonia, ARDS) requiring hospitalization[4] and without alternative explanatory diagnosis (e.g., influenza)[6] 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

- NCSLPH has completed verification of the CDC 2019-nCoV real-time RT-PCR Diagnostic Panel which has been granted Emergency Use Authorization (EUA) from the FDA.
    - FDA EUA Fact Sheet for Healthcare Providers
    - FDA EUA Fact Sheet for Patients

- Health care providers in consultation with the state Communicable Disease Branch (919-733-3419, available 24/7) or local public health department will conduct a risk assessment to determine if individuals meet the NC criteria for diagnostic testing to detect COVID-19. When the criteria are met, a NC Patient Under Investigation (PUI) number is assigned, documenting approval for testing.
- **Prior approval from the Communicable Disease Branch is required for submission of specimens.**

Specimen Collection

- Specimens should be collected as soon as possible once a PUI is identified, regardless of the time of symptom onset.
- Health care providers or public health personnel collecting specimens should wear recommended PPE as described in the *What Healthcare Personnel Should Know about Caring for Patients with Confirmed or Possible COVID-19 Infection*
- For initial diagnostic testing to detect COVID-19, NC 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.
    - 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.
        - *Nasopharyngeal swab:* Insert a swab into the nostril parallel to the palate until resistance is encountered. Leave the swab in place for a few seconds to absorb secretions.
        - *Oropharyngeal swab (e.g., throat swab):* Swab the posterior pharynx and tonsillar areas, avoiding the tongue, teeth, and gums.
    - 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.
- Label each specimen with the patient's name, patient's PUI number or date of birth and date and time of collection.
- Store specimens at 2-8°C for up to 72 hours following collection. If longer storage is required, store at -70°C.
- Additional guidance on collection, handling, and testing of clinical specimens is provided at the following locations:
    - https://slph.ncpublichealth.com/bioterrorism/2019-ncov.asp
    - https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html

Specimen Packaging and Shipment

- Contact the Bioterrorism and Emerging Pathogens' Duty Phone (919-807-8600) prior to any shipment to coordinate transportation.
    - Specimens should be shipped as UN3373 Category B.
        - *Sentinel Level Clinical Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases, Packing and Shipping Infectious Substances*
    - Depending on the case, a DASH courier may be arranged by the Bioterrorism and Emerging Pathogens' Duty staff.
    - Alternatively, direct shipment of specimens to the NCSLPH via overnight commercial courier will be coordinated.

        - Ship refrigerated specimens to NCSLPH on frozen cold packs
        - If a specimen is frozen at -70°C, ship on dry ice.
        - Shipping address:
          Attention: Virology/Serology Unit
          North Carolina State Laboratory of Public Health
          4312 District Drive
          Raleigh, NC 27607-5490
        - Send overnight courier package tracking number to slph.covid19@dhhs.nc.gov
- All specimen submissions **must** have a completed NCSLPH Virology/Serology Form

Specimen Rejection Criteria

- Samples without a PUI number and Communicable Disease Branch approval for testing.
- Specimens not kept at 2-8°C (≤72 hrs) or if specimens have not been frozen at -70°C and they are > 72 hrs old.
- Incomplete specimen labeling or documentation.
- Inappropriate specimen type.
- Insufficient specimen volume for testing.

Result Reporting

- Turn-around time for testing will be dependent on testing volumes.
- Specimens testing positive at the NCSLPH will be reported as "Presumptive positive 2019-nCoV"
    - The specimen will be immediately shipped to the CDC for confirmatory testing.
    - Presumptive positive results are public health actionable.
    - Confirmatory results are expected 24-72 hrs following receipt at CDC, depending on testing volume.
- Specimens testing negative at the NCSLPH will be reported as 2019-nCoV "Not Detected."

Clinical Laboratory Safety Guidance

- Laboratorians should use appropriate precautions when handling specimens that may contain SARS-CoV-2. Timely communication between clinical and laboratory staff is essential to minimize the risk associated when handling specimens from patients with possible COVID-19**. Such specimens should be labeled accordingly**, and the laboratory should be alerted to ensure proper specimen handling.
    - Additional information can be found in:
        - The CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

Additional Information for Clinical Laboratory Testing

- Specimens initially tested in a clinical diagnostic laboratory regulated by CLIA using a laboratory developed test (LDT) must abide by FDA regulations that require registration of the assay employed.
    - *Policy for Diagnostic Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to EUA for Coronavirus Disease-2019 during the Public Health*

Requests for Additional Information From NCSLPH

- For general information, non-urgent LABORATORY questions about specimen collection, testing, and reporting please email the NCSLPH COVID-19 helpdesk at slph.covid19@dhhs.nc.gov.
- **For urgent questions, please contact the Bioterrorism and Emerging Pathogens' Duty Phone at 919-807-8600**

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.