NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

March 8, 2020 (*replaces version dated March 2, 2020*)

To: All North Carolina Clinicians and Laboratories
From: Jean-Marie Maillard, MD, MSc, Medical Director, Communicable Disease Branch
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:

- Updated criteria to guide evaluation for persons under investigation for COVID-19 to include international and US geographically affected areas,
- New commercial laboratory testing availability, and
- Isolation guidance for those undergoing testing for COVID-19.

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. The World Health Organization 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/coronavirus/providers.html

Case Investigation and Testing

Clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Decisions on which patients receive testing should be based on the local epidemiology of COVID-19, as well as the clinical course of illness. Most patients with confirmed COVID-19 have developed fever[1] and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). Clinicians are strongly encouraged to also consider and test for other causes of respiratory illness, including infections such as influenza.

Testing at the North Carolina State Laboratory of Public Health (NCSLPH) is available with prior approval by the epidemiologist on call due to limited availability of testing. Patients meeting the following criteria for a Person Under Investigation (PUI) will be considered for testing at NCSLPH:

1) Fever[1] OR signs/symptoms of lower respiratory illness (e.g., cough, shortness of breath) in any person, including healthcare workers[2], who has had close contact[3] with a laboratory-confirmed[4] COVID-19 patient within 14 days of symptom onset.

2) Fever[1] AND signs/symptoms of lower respiratory illness (e.g., cough, shortness of breath) AND negative PCR influenza test[5] in any person with history of travel from affected geographic areas[6] within 14 days of symptom onset.

3) Fever[1] with unexplained acute lower respiratory illness (e.g., pneumonia, ARDS) requiring hospitalization where no source of exposure has been identified with, at a minimum, negative PCR influenza test[5].

New commercial laboratory testing is available. Testing is not recommended for asymptomatic persons. Prior authorization for testing is **not** required for commercial lab testing **but** patients being tested will be considered a PUI and *must be isolated* either at home or in a hospital based on their need for care. Providers should 1) give the attached home isolation document to all patients being tested by a commercial lab that do not require hospitalization, and 2) complete and submit the attached PUI form to the patient's local health department at the time the test is ordered. These documents can also be found here.

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.**
- 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.

Control Measures

- Patients undergoing testing will be considered a PUI. Providers should give the isolation guidance to all patients.
- Isolation can be discontinued if 1) the initial test is negative, or 2) by public health officials on the basis of 2 negative test results conducted on specimens collected at least 24 hours apart.

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 is currently conducting testing to detect COVID-19 using 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
- **The NCSLPH requires approval from the Communicable Disease Branch** prior to testing for COVID-19. 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 at the SLPH. When the criteria are met, a NC Patient Under Investigation (PUI) number is assigned, documenting approval for testing.
- **New** commercial laboratory testing is available and should be limited only to symptomatic persons. Prior authorization is **not** required for commercial laboratory testing **but** individuals will be considered a PUI.
- Persons in whom COVID-19 infection is suspected should also be evaluated for common causes of community-acquired respiratory illness, if not already done. In persons who are close contacts of known cases, state and local public health should be consulted even if the patient tests positive for another respiratory pathogen. Note: For biosafety reasons, viral culture should not be attempted in cases meeting the PUI criteria.
- Point-of-Care tests which are not FDA approved should not be used

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 medium. 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. Slowly remove swab while rotating it. Place the tip into the vial of sterile viral transport medium. Aseptically cut off the applicator stick so that it does not protrude above the rim of the tube and cap. **LABEL THE VIAL NP**, include 2 unique identifiers (described below) and date/time of collection.
        - *Oropharyngeal swab (e.g., throat swab):* Swab the posterior pharynx and tonsillar areas, avoiding the tongue, teeth, and gums. Place the tip into the vial of sterile viral transport medium. Aseptically cut off the applicator stick so that it does not protrude above the rim of the tube and cap. **LABEL THE VIAL OP**, include 2 unique identifiers (described below) and date/time of collection.
    - 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 such as a 50 ml conical tube .
- Label each **NP/OP** specimen accordingly 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

- Specimens should be packaged and 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 contacting the Bioterrorism and Emerging Pathogens' Duty Phone at (919) 807-8600.
- All other approved specimens should be directly shipped to the NCSLPH via overnight commercial courier.
    - 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 fully 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. **Viral transport media not labeled with the collection site, NP vs. OP will be rejected.**
- 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*
- Specimens tested to detect COVID-19 at clinical laboratories can be submitted to the NCSLPH for confirmatory testing.
    - Contact Communicable Disease Branch (919-733-3419, available 24/7) to notify about positive result.
    - Follow the guidance above for specimen packaging, shipping and submission.
    - When completing the NCSLPH Virology/Serology Form, include information regarding the test that was conducted and the results that were obtained.

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 critical laboratory-related questions during normal business hours (8am – 5pm, Monday – Friday) please call the SLPH Customer Service line at 919-733-3937.
- For critical laboratory-related questions after business hours and on weekends, 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]For healthcare personnel, testing may be considered if there has been exposure to a person with suspected COVID-19 without laboratory confirmation

[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]Documentation of laboratory-confirmation of COVID-19 may not be possible for travelers or persons caring for COVID-19 patients in other countries.

[5]If PCR influenza testing is not available in a timely manner, testing can be arranged through discussion with the epidemiologist on call.

[6] 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 AND King and Snohomish counties in WA. See all COVID-19 Travel Health Notices.