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Division of Public Health

March 16, 2020 (*replaces version dated March 13, 2020*)

To: All North Carolina Clinicians and Laboratories
From: Zack Moore, MD, MPH, State Epidemiologist
Scott Shone, PhD, HCLD (ABB), Public Health 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:

- Emphasize commercial laboratory testing availability,
- Updated guidance for discontinuation of isolation for Persons Under Investigation,
- Clarifications to infection prevention and control guidance, and
- Updated procedures for testing approval from local health departments.

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 fever¹ 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.

Commercial laboratory testing to detect COVID-19 is now available. Testing should not be done for asymptomatic persons. Prior authorization for testing is **not** required for commercial lab testing **but** patients being tested will be considered persons under investigation (PUIs) and **must be isolated** either at home or in a hospital based on their need for care. Providers should 1) give the home care isolation document to all patients being tested that do not

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require hospitalization, and 2) complete and submit the PUI form to the patient's local health department at the time the test is ordered. These documents can be found [here](#) under "Patients Under Investigation."

Testing at the North Carolina State Laboratory of Public Health (NCSLPH) is available with prior approval by the local health department for the patient's county of residence, or the state epidemiologist on call (919-733-3419). Patients meeting the following criteria for a Person Under Investigation (PUI) will be considered for testing at NCSLPH:

- 1) Fever¹ OR signs/symptoms of lower respiratory illness (e.g., cough, shortness of breath) in any person, including healthcare workers², who has had close contact³ with a laboratory-confirmed⁴ COVID-19 patient within 14 days of symptom onset.
- 2) Fever¹ AND signs/symptoms of lower respiratory illness (e.g., cough, shortness of breath) AND negative influenza test (rapid or PCR) and no other more likely diagnosis.

Patients seeking medical care should NOT be referred to NC COVID-19 Call Center or the state epidemiologist on-call line. The Call Center line is intended to provide general information and the epidemiologist on-call line is intended for clinicians and local health departments needing consultation.

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 PUI. Providers should give the [PUI Isolation Guidance](#) to all patients undergoing testing.
- Isolation can be discontinued if the test is negative. If the test is positive, the patient should remain isolated until one of the following criteria is met:
 - At least 7 days since symptom onset **and** ≥72 hours after symptom resolution (absence of fever without the use of fever-reducing medication and improvement in respiratory symptoms), whichever is longer, OR
 - Absence of fever (without use of fever-reducing medication), improvement in respiratory symptoms, and 2 negative test results conducted on specimens collected at least 24 hours apart.
- Healthcare providers and others who work in high-risk settings should check with their employer or occupational health program to determine whether additional criteria must be met before return to work.

Infection Control

- To reduce unnecessary exposures, NC DHHS encourages healthcare facilities and providers to maximize the use of:
 - Alternate telehealth options including triage phone lines and on-line patient portals, and
 - Engineering and administrative controls such as prompt detection, effective triage and patient isolation. See [Hierarchy of Controls](#) for more information.
- On March 10, CDC updated PPE recommendations for the care of patients with known or suspected COVID-19. Surgical face masks are an acceptable alternative to respirators (e.g., N95).
 - Current recommendations include the use of:
 - Surgical face mask OR fit-tested NIOSH-approved N95 or higher-level respirators
 - Gowns, gloves and eye protection (e.g., goggles or face shield)
 - Private room with the door closed

- IF conducting an aerosol-generating procedure (e.g., nebulizer treatment, intubation), then a respirator (e.g., N95) should be worn (not a facemask) and the procedure should be conducted in a negative pressure room (e.g., AIIR).
- Patients should be asked to wear a surgical mask as soon as they are identified as having symptoms of respiratory illness.
- Patients with known or suspected COVID-19 should continue to wear a mask when healthcare providers are present in room or if they must be moved from their room.
- As the situation continues to evolve, please find updated [CDC](#) guidance.

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

- **Commercial laboratory testing is now 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.
- **The following guidance only applies to testing at the NCSLPH, and refer to any commercial laboratory guidance when using those services.**
- 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](#)
- **Patients must meet the testing criteria given in this document.** When the criteria are met, a NC Patient Under Investigation (PUI) case file is created in REDCap and a REDCap# is subsequently generated documenting approval for testing. The REDCap# will be referenced on the laboratory testing report form under 'NC PUI Number'.
- Point-of-Care tests which are not FDA approved should not be used.

Specimen Collection

- [Specimen Collection and Shipping Instructions](#)
- For diagnostic testing to detect COVID-19, **only a nasopharyngeal swab should be collected.** The specimen should be collected as soon as possible once a PUI is identified, regardless of the time of symptom onset.
 - Nasopharyngeal swab collection:
 - 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.
 - To collect the nasopharyngeal specimen, place the 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 a vial of sterile 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 swab with 2 unique identifiers** (i.e. patient's name and date of birth) and date of collection. **DO NOT LABEL THE CONICAL TRANSPORT TUBE without labeling the vial.**
- 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](#)
- All specimens approved for testing at the NCSLPH should be directly shipped to the NCSLPH via overnight commercial courier or delivered via private courier (e.g., hospital couriers). **All shipments must follow these guidelines:**
 - Ship refrigerated specimens to NCSLPH on frozen cold packs
 - If a specimen is frozen at -70°C, ship on dry ice.
Specimen deliveries will be received at the NCSLPH loading dock from 7am-5pm Monday through Friday, and 8am-12pm on Saturday and Sunday.
 - Shipping address:
Attention: Virology/Serology Unit COVID-19
North Carolina State Laboratory of Public Health
4312 District Drive
Raleigh, NC 27607-5490
 - If using SLPH collection kits and shipping specimens on a Friday for an overnight Saturday delivery, you must email slph.covid19.tracking@dhhs.nc.gov by noon on Friday to request a Saturday delivery return service label, which will then be emailed to you. No return shipping labels are provided on Saturdays or Sundays.
 - Email slph.covid19.tracking@dhhs.nc.gov with the tracking number or private courier arrival information and the number of specimens being sent.
- All specimen submissions **must have a fully completed [NCSLPH Virology/Serology Form](#)**, using the EIN number specific to the submitter's facility.

Specimen Rejection Criteria

- Specimens without a REDCap# or not meeting the approval criteria given in this document 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. **Unlabeled vials containing the NP swab will be rejected.**
- Inappropriate specimen type.
- Insufficient specimen volume for testing.

Result Reporting

- Turnaround time for testing will be dependent on testing volumes.
- NCSLPH electronic reports are posted on our CELR (Clinical and Environment Laboratory Reports) online system.
 - [Set up a CELR Account](#) – Requires the facility's unique EIN
 - [CELR Tutorial](#)
- Specimens testing positive at the NCSLPH will be reported as "Positive 2019-nCoV"
- 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 \(COVID-19\)](#)

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.

Requests for Information from Communicable Disease Branch

- For members of the public, please call the NC COVID-19 Call Center at 866-462-3821.
- For non-urgent questions, please email ncresponse@dhhs.nc.gov.

Notes:

¹Fever 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.

²For healthcare personnel, testing may be considered if there has been exposure to a person with suspected COVID-19 without laboratory confirmation

³Close 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, face mask or 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.

⁴Documentation of laboratory-confirmation of COVID-19 may not be possible for travelers or persons caring for COVID-19 patients in other countries.