



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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Division of Public Health

March 10, 2020 (*replaces version dated March 8, 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:

- Updated criteria to guide evaluation for patients under investigation for COVID-19,
- Updated guidance for discontinuation of isolation for Persons Under Investigation.
- Updated specimen collection instructions, specifically to include NP and OP swabs in a single tube, and
- Storage of any unused portions of NCSLPH COVID-19 specimen collection kits for future use.

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.

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

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF PUBLIC HEALTH

LOCATION: 5605 Six Forks Road, Building 3, Raleigh, NC 27609
MAILING ADDRESS: 1931 Mail Service Center, Raleigh, NC 27699-1931
www.ncdhhs.gov • TEL: 919-707-5000 • FAX: 919-870-4829

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

- 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.

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 PUIs and **must be isolated** either at home or in a hospital based on their need for care. Providers should 1) give the home isolation document to all patients being tested that do not 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 also be found [here](#) under "Patients Under Investigation."

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 Guidance for Persons Under Investigation 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 cleared by local public health officials.

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](#)
- If using an SLPH collection kit and mailing specimens on a Friday for an overnight Saturday delivery, you must email slph.covid19@dhhs.nc.gov to request a Saturday delivery return service label, which will then be emailed to you. **The NCSLPH requires approval from either the Local Health Department where the provider is located or the State 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 their [local 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) case file is created in REDCap and a REDCap ID is subsequently generated documenting approval for testing. The REDCap ID will be referenced on the laboratory testing report form under 'NC PUI Number'.
- **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.
- 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 a respiratory pathogen other than flu. 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 [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) should be collected separately and **both swabs should be placed into one vial of transport medium.**
 - 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 both NP and OP swabs immediately into a single sterile tube containing 2-3 ml of viral transport medium.
 - 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 the 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. Cap the vial.
 - To collect the oropharyngeal specimen (e.g., throat swab) use a fresh swab to swab the posterior pharynx and tonsillar areas, avoiding the tongue, teeth, and gums. Uncap the vial of transport medium with the NP swab and place the fiber end of OP swab into the same vial. Aseptically cut off the applicator stick so that it does not protrude above the rim of the tube and cap vial. **LABEL THE VIAL:** NP/OP and include the patient's name, date of birth, REDCap#, 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 THE TUBE:** Sputum and include the patient's name, date of birth, REDCap#, and date/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>

Note: For local health departments that have previously ordered and received NCSLPH COVID-19 Specimen Collection Kits, unused collection materials can be kept for future use. Unused vials of viral transport medium should be stored at 2-8°C.

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 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.
 - Specimens should be shipped Monday – Friday using a commercial overnight courier
 - Shipping address:
Attention: **Virology/Serology Unit COVID-19**
North Carolina State Laboratory of Public Health
4312 District Drive
Raleigh, NC 27607-5490
 - If using an SLPH collection kit and mailing specimens on a Friday for an overnight Saturday delivery, you must email slph.covid19@dhhs.nc.gov to request a Saturday delivery return service label, which will then be emailed to you.
 - 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 REDCap ID or Local Health Department/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

- Turnaround 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 hours 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](#)
- Immediate notification of the detection of COVID-19 to the Communicable Disease Branch (919-733-3419, available 24/7) is required.

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:

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, 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.