



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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March 23, 2020 (*replaces version dated March 16, 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 (7 pages)

This update is intended to provide the latest information to all North Carolina clinicians and laboratory staff regarding the Coronavirus Disease 2019 (COVID-19). Please read thoroughly as there are several updates, including:

- Changes in testing recommendations: **People with mild symptoms consistent with COVID-19 do NOT need testing and should be instructed to stay at home to recover.** Mild symptoms defined as fever and cough without any of the following: shortness of breath, difficulty breathing, chest discomfort, altered thinking, cyanosis
- Updated procedures for testing approval from local health departments
- Updated guidance for discontinuation of isolation
- Updated categories of persons at higher risk for severe illness

North Carolina's response to COVID-19 will continue to rapidly evolve. The most up to date information and guidance can be found at <https://www.cdc.gov/coronavirus/2019-ncov/index.html> and <https://www.ncdhhs.gov/coronavirus>.

Background:

The respiratory disease named "coronavirus disease 2019" (abbreviated "COVID-19"), caused by a novel coronavirus named "SARS-CoV-2", was declared a pandemic by the World Health Organization on March 11, 2020.

North Carolina now has community transmission of COVID-19. Therefore, we are moving to a different phase of our response efforts and will be further increasing our population-based community mitigation strategies. The goal of mitigation is to decrease spread of the virus among our population – especially for those who are at highest risk of clinical severity, and our health care workers – so fewer people need medical care at the same time. In addition, we need to implement strategies to conserve supplies and capacity so our health care workers can care for people who need medical attention even during the peak of the outbreak.

Rationale for updated testing recommendations:

To decrease acceleration of spread in community and exposures in healthcare settings

1. People infected with SARS-CoV-2 (virus causing the disease COVID-19) coming out to be tested may spread illness to others in the community, including those at higher risk of complications, and health care workers.

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2. People who are not infected with SARS-CoV-2 can become so when seeking testing, especially at health care sites.

To preserve resources

1. Personal Protective Equipment and supplies will be needed for outbreaks in high-risk settings (e.g. long-term care), to protect frontline workers (e.g. health care workers, first responders), and to care for people with more severe clinical symptoms.

No impact on management for most people

1. For those with mild symptoms, treatment is supportive and focused on symptom management.
2. A test will not change management.

Alternative surveillance tools can be used to track the spread of COVID-19

1. Tracking only lab-confirmed cases is not a reliable or accurate way to understand the pandemic.
2. We will use influenza surveillance tools, which are designed to track widespread respiratory illness.

Clinical assessment, Case Investigation and Testing

- Clinicians should use, to the extent possible, telehealth/televideo and telephone triage to assess clinical status of patients with respiratory illnesses.
- Telehealth/televideo and telephone triage are critical tools to allow patients with mild symptoms to have safe access to appropriate assessment, clinical guidance and follow up, and self-care information, while preventing further spread of COVID-19 or exposing patients to COVID-19 in a medical setting.
- Telehealth is broadly being covered at parity for most patients with private insurance, Medicare and Medicaid and therefore should be used whenever clinically appropriate in lieu of face-to-face encounters.
- Clinicians should use their judgment to determine if a patient has mild signs and symptoms compatible with COVID-19 (e.g., fever and cough) or more severe symptoms requiring in-person medical care (e.g. shortness of breath, difficulty breathing, chest discomfort, altered thinking, cyanosis).
- **In general, patients who have mild symptoms consistent with COVID-19, do not need testing for COVID-19 and should be instructed to stay and recover at home.** This strategy is consistent with [guidance](#) from the Centers for Disease Control and Prevention.
- Patients should be counseled to call if they have worsening signs or symptoms of respiratory illness (e.g. increasing fever, shortness of breathing, difficulty breathing, chest discomfort, altered thinking, cyanosis).
- Patients in [high risk categories for clinical severity](#) (e.g., 65 year and older, chronic lung disease or moderate to severe asthma, heart disease, severe obesity BMI ≥ 40 , other underlying poorly controlled chronic health conditions such as diabetes, renal failure, liver disease, and immunocompromised) should have more frequent follow up to assess clinical status. Pregnant women should be monitored closely as they are known to be at risk with severe viral illness, however, to date data on COVID-19 has not shown increased risk. While children are generally at lower risk for severe illness, some studies indicate a higher risk among infants.
- **Escalating medical care should occur if symptoms worsen.**
- Testing to detect COVID-19 is available through commercial and health system labs and the **NC State Laboratory of Public Health (NCSLPH)**.
- Testing should **not** be done for asymptomatic persons.
- In general, patients with mild illness (defined above) do not need testing.
- Clinicians should use their clinical judgement and prioritize testing of patients with more severe respiratory symptoms; patients for whom clinical management would be different if they were infected with COVID-19; patients in high-risk settings (e.g., congregate care settings, long term care); and health care workers and first responders.
- For patients who have more significant symptoms and do need medical attention, clinicians are strongly encouraged to also consider and test for other causes of respiratory illness, including infections such as influenza.

Testing at the NC State Laboratory of Public Health (NCSLPH):

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 must meet at least one of the following criteria to 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.

OR

- 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.

Prior approval by public health is **not** required for commercial lab testing. Clinicians should use their clinical judgement and prioritize testing of patients with more severe respiratory symptoms; patients for whom clinical management would be different if they were infected with COVID-19; patients in high-risk settings (e.g., congregate care settings, long term care); and health care workers and first responders.

Patients undergoing testing will be considered a person under investigation (PUI). Providers should give the [Person Under Investigation Guidance \(Spanish\)](#) to all patients undergoing testing and ensure patients are aware that they are expected to stay in isolation until results are back and longer if they are positive. Submitters will receive results and should inform patients of result. If the result is positive, further isolation may be required in coordination with the local health department.

Patients seeking medical care should NOT be referred to the 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 a patient is tested for SARS-CoV-2 infection.
- 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 who have symptoms consistent with COVID-19 should self-isolate for
 - At least 3 days (72 hours) have passed *since recovery* defined as resolution of fever without the use of fever-reducing medications **and** improvement in respiratory symptoms (e.g., cough, shortness of breath), **and**
 - At least 7 days have passed *since symptoms first appeared*.
- Patients with clinical COVID-19 infection do NOT need a negative COVID-19 test result to document recovery.
- Additional criteria for discontinuing isolation may be required for patients requiring hospital admission.
- Close contacts of a person with known or suspected COVID-19 should self-monitor their temperature and symptoms of COVID-19, limit outside interaction as much as possible for 14 days, and self-isolate if they develop symptoms.
 - Specific guidance for healthcare workers with potential exposures is available at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html>.

- 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 returning to work.

Infection Control

- To reduce unnecessary exposures, NC DHHS encourages healthcare facilities and providers to maximize the use of:
 - Telehealth/televideo and telephone triage to assess clinical status of patients with respiratory illnesses. Telehealth is broadly being covered at parity for most patients with private insurance, Medicare and Medicaid so should be used whenever clinically appropriate in lieu of in-person encounters.
 - Engineering and administrative controls such as prompt detection, effective triage and patient isolation. See [Hierarchy of Controls](#) for more information.
- 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.
- Healthcare facilities and systems are encouraged to establish designated areas and teams for patients with suspected COVID-19 to the extent possible.
- Health care teams should wipe down surfaces with [EPA registered disinfectant effective against coronaviruses](#) in between patient consults.
- Hospitals and other healthcare settings should consider routine use of face masks and gloves for all patient interactions, if supplies are sufficient.
- Clinicians should wear respiratory protection for interview and examination of patients with respiratory illnesses. Either surgical mask or N-95 respirator are appropriate.
- On March 10, the CDC updated PPE recommendations for the care of patients with known or suspected COVID-19. [Surgical face masks are an acceptable alternative to respirators \(e.g., N95\)](#) if not performing an aerosol-generating procedure
 - 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).
- As the situation continues to evolve, please find updated [CDC](#) guidance.

Treatment

- At this time, no vaccine for COVID-19 is available and no specific treatment for COVID-19 is approved by the FDA.
- Hospitals caring for severely ill patients are encouraged to explore options for clinical trials or other options for access to investigational treatments.
- Studies with small numbers of patients suggest that hydroxychloroquine could reduce the length of hospital stay and improve COVID-19 pneumonia in severely ill patients. Current data are not conclusive on patients with mild symptoms. We continue to review the evidence as it becomes available.
- Other medications in testing for COVID-19 are FDA approved to treat serious diseases, such as tuberculosis, HIV infection, and autoimmune conditions. It is important that those medications remain available to treat the conditions for which they are FDA approved as their effectiveness for COVID-19 is being assessed.
- Corticosteroids should be avoided unless indicated for other reasons (for example, chronic obstructive pulmonary disease exacerbation or septic shock).

Testing

- The following guidance only applies to testing at the NCSLPH. 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 the 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 8am-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

- 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 ncrespone@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.