



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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Division of Public Health

March 29, 2020 (*replaces version dated March 23, 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 memo updates previous guidance shared on March 23rd, 2020. It 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:

- Updated criteria for submission of specimens to the North Carolina State Laboratory of Public Health
- Providers no longer asked to fill out person under investigation forms for patients tested for COVID-19
- Requirement for reporting of COVID-19-associated deaths

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 widespread 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– so fewer people need medical care at the same time. In addition, we need to implement strategies to conserve supplies and capacity and critical infrastructure workforce, so our health care workers and first responders can care for people who need medical attention even during the peak of the outbreak.

Clinical Assessment and Management

- Clinicians should encourage their patients to call if they have medical concerns before seeking care in-person.
- 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.

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

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

- 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 in non-congregate settings who have mild symptoms compatible with COVID-19 that do not progress 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. Additional information about this recommendation is provided at the end of this document.
- 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 \geq 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.**

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.

Testing for SARS-CoV-2

Testing to detect SARS-CoV-2 is available through the North Carolina State Laboratory of Public Health (SLPH) for patients meeting criteria specified in this document. Testing is also available through some commercial and health system laboratories.

Prior approval by public health is not required for testing at commercial or hospital-based laboratories. However, clinicians are encouraged to consider the following recommendations:

- Testing is not recommended for asymptomatic persons.
- In general, patients in non-congregate settings with mild illness that does not progress (defined above) do not need testing.
- Clinicians should use their clinical judgement and prioritize testing of patients with more severe respiratory symptoms; hospitalized patients; patients for whom clinical management would be different if they were infected with COVID-19; patients in high-risk settings (e.g., congregate living 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.

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 should establish a clear plan with patients to inform them of their results. If the result is positive, further isolation may be required in coordination with the local health department. Providers are no longer being asked to fill out and submit a PUI form to the local health department for every patient for whom testing is ordered. Physicians and laboratories are still required to report suspected or confirmed cases of novel coronavirus infection to the state or local public health department via telephone or facsimile with basic contact information of the case. This is particularly important in high-risk settings such as congregate living facilities.

Updated Criteria for SARS-CoV-2 Testing at the NC State Laboratory of Public Health (NCSLPH):

Clinicians can submit specimens to the State Laboratory of Public Health for person *with symptoms compatible with COVID-19** who are in one of the following four categories:

1. Hospitalized patients
2. Healthcare workers or first responders (e.g., EMS, law enforcement, fire department)
3. Patients who live in or have regular contact with a high-risk setting (e.g. long-term care facility, homeless shelter, correctional facility, migrant farmworker camp)
4. [Persons who are at higher risk of severe illness](#) and for whom a clinician has determined that results would inform clinical management

**Most patients with confirmed COVID-19 have developed fever (subjective or objective) and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing).*

Prior public health approval is not required to submit specimens for persons in one of these four categories. See additional information in this document for specific submission instructions. To discuss testing for patients not meeting these criteria, contact the Division of Public Health epidemiologist on call line at 919-733-3419.

In order to systematically monitor COVID-19 virus activity in North Carolina, NCSLPH will also perform testing on specimens submitted from sites participating in the U.S. Outpatient Influenza-like Illness Surveillance Network ([ILINet](#)).

Reporting

- Effective February 3, 2020, physicians and laboratories in North Carolina are required to immediately report suspected or confirmed cases of novel coronavirus infection to state or local health departments via telephone or facsimile of basic contact information of the case. This is particularly important in high-risk settings such as congregate living facilities
- Effective March 23, 2020, physicians in North Carolina are required to report any COVID-19-associated death within 24 hours.
- Any cluster of severe acute respiratory illness in healthcare workers in North Carolina should prompt immediate notification of local or state public health for further investigation and testing.

Control Measures

- Patients who have mild symptoms consistent with COVID-19 and can recover at home should self-isolate for
 - At least 7 days have passed *since symptoms first appeared*.
 - **and** 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)
- Notably, patients with clinical COVID-19 infection, in general, do NOT need a negative COVID-19 test result to document recovery, if they meet the clinical criteria.
- Additional criteria for discontinuing isolation may be required for [patients requiring hospital admission](#) and for [immunocompromised persons](#).
- Household members and other close contacts (within 6 feet for a prolonged period of time) of a person with known or suspected COVID-19 should stay at home for 14 days after the last exposure, maintain physical distance (at least 6 feet) from others, self-monitor their temperature and symptoms, 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 workers 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.
- Special considerations and specific guidance may be needed for other critical infrastructure workers.

Infection Control

To reduce unnecessary exposures, NC DHHS encourages healthcare facilities and providers to maximize the use of

- Telehealth for symptom assessment and management as described above
- Engineering and administrative controls such as prompt detection, effective triage and patient isolation. See [Hierarchy of Controls](#) for more information.
 - Schedule patients with respiratory illness at a time that may be less busy (e.g., beginning of the day or end of the day) and flag that the patients has flu-like symptoms, so they are identified ahead of time.
 - Post signs on entrance instructing patients to alert staff if they have respiratory symptoms as soon as they arrive.
 - Patients should be asked to wear a surgical mask as soon as they are identified as having symptoms of respiratory illness and isolated in a separate area or private, well-ventilated room or as soon as possible.
 - Front desk and triage personnel should use physical barriers (such as windows) when possible or maintain spatial distance of 6 ft from patient with respiratory illness. No specific personal protective equipment is required for these staff members.
 - 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 established designated areas, sites, 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 and 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.
 - Use Strategies for Preservation and Management of Scarce Medical Resources.
 - [Strategies for Scarce Resource Situations](#) (March 13, 2020)
 - [NC Healthcare Supply Conservation Considerations](#) (Feb. 27, 2020)
 - [DOL Interim Guidance on COVID-19 Use of Filtering Facepiece Respirators After Their Expiration Date](#) (March 13, 2020)

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.

- [Information](#) about therapeutic options is available from the CDC
- There currently is not any evidence to support using any medications for prophylaxis for COVID-19
- Many medications being evaluated for effectiveness in treating or prevention COVID-19 are FDA approved to treat other serious diseases, such as tuberculosis, HIV, and autoimmune conditions. It is important that those medications remain available to treat the conditions for which they are FDA approved.
- The North Carolina Board of Pharmacy and the North Carolina Board of Medicine have passed emergency rules that create a list of “restricted drugs” to ensure continued availability of these medications. The Board of Pharmacy emergency rule is available at <http://www.ncbop.org/LawsRules/COVID19DrugPreservationRule21NCAC46.1819.pdf>
- Corticosteroids should be avoided unless indicated for other reasons (for example, chronic obstructive pulmonary disease exacerbation or septic shock).

Additional Information for Testing at NCSLPH

The following guidance only applies to testing at the NCSLPH. Refer to any commercial or healthcare system 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](#)

Submission instructions

- **Prior approval is no longer required for submission to the NCSLPH, if patients meet the updated criteria.**
- COVID-19 testing can now be ordered by healthcare providers and local health departments using the **new [COVID-19 Form submission form](#)**
- A PUI/REDCap# is no longer required for COVID-19 testing; however, providers are still required to immediately report suspected or confirmed novel coronavirus infections to state or local public health.

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 any crush-proof transport containers without labeling the specimen 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 should be directly shipped to the NCSLPH via overnight commercial courier or delivered via private courier (e.g., hospital couriers). Do not use the State Courier.
- **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
- All specimen submissions **must have a fully completed [COVID-19 Form](#)**, using the EIN number (Tax ID) specific to the submitter’s facility.

Specimen Rejection Criteria

- 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 General Information About Coronavirus

- 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.

For more information

1. NCDPH coronavirus website: www.ncdhhs.gov/divisions/public-health/coronavirus-disease-2019-covid-19-response-north-carolina.
2. NC DHHS Guidance health care providers: <https://www.ncdhhs.gov/covid-19-guidance#all-guidance-for-health-care-providers-and-local-health-departments>
3. Patient Guidance
 - What to do if you feel sick in [English](#) and [Spanish](#) (March 23, 2020 - NCDHHS)
 - [10 ways to manage your symptoms at home](#) (CDC)
 - [Caring for someone sick at home](#) (CDC)
 - [What to do if you are sick with COVID-19 or think you might have it](#) (CDC)
4. CDC website on health care facility preparedness <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/steps-to-prepare.html>.

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.
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.