NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

Overview of NC's Testing Approach

September 25, 2020

Testing is a central pillar of North Carolina's multi-faceted strategy to combat COVID-19 to

- **Slow the Spread – Prevention**
- **Know Who Has COVID-19 and Who Has been Exposed – Testing and Contact Tracing**
- **Supporting People to Stay Home – Quarantine and Isolation**

Access to testing is essential to supporting and protecting our communities and to understanding the prevalence of the virus in our state to inform public health policy. Since the start of the pandemic, North Carolina significantly ramped up its testing capacity from fewer than 10,000 per day in May to now being one of the top ten states in the country for total number of COVID-19 tests with results according to the Kaiser Family Foundation. These efforts are detailed in the ELC State testing plan submitted to the U.S. Department of Health and Human Services. In line with the latest guidance from the Centers for Disease Control and Prevention (CDC) on SARS-CoV-2 (COVID-19) diagnostic (molecular or antigen) testing, North Carolina continues to recommend testing for people who have symptoms or think they have been exposed to COVID-19.

North Carolina stakeholders aligning around a common testing strategy will enhance the state's ability to slow the spread of COVID-19 and maximize value from public and private investments. Increasing laboratory or field testing capacity alone is not the only element of a testing strategy; it must be coupled with demand-side interventions like clear, proactive community outreach, targeted access to testing for high-risk settings, and public messaging to ensure that testing capacity is used most effectively.

North Carolina's testing strategy is based on five priorities:

1. **Ensure access to testing**, especially for high-risk populations
2. **Diversify testing modalities,** using scientifically and technically diverse methods
3. **Build testing capacity,** relying on a diverse ecosystem of labs for sufficient volume
4. **Leverage public and private funding**
5. **Monitor, learn, and adapt**

1. Ensure access to testing

North Carolina's goal is to ensure that everyone who needs a test can get one. Further, the state prioritized using state and federal resources for populations that have been disproportionately impacted by COVID-19, those at high risk of exposure, those at high risk of serious illness, and those living in areas with otherwise limited testing availability. This approach is consistent with the emerging guidance that suggests tailoring testing approaches to individual risk profiles, taking into consideration factors like where people live and work, historically marginalized populations and people with underlying health conditions, and people with higher risk of both infection and poor outcomes, including death.

Currently frequency levels are informed by state and national public health experts and federal guidance. North Carolina will continue to adapt its approach based on emerging science. The Department continues to closely monitor emerging outbreaks and may recommend periodic testing for additional populations as needed.

As of September 2020, examples of the state's approach in action include the following:

- Paying for community testing events in census tracts that have significant Black/African American and/or Latinx/Hispanic populations and limited to no existing testing sites.
- Conducting baseline testing of all skilled nursing facility residents and staff, issuing a Secretarial Order to require testing every other week (biweekly) of all skilled nursing facility staff, and paying for biweekly testing through November 2020. NCDHHS guidance requires skilled nursing facility staff to be tested weekly if a COVID-19 case has been detected. Bringing these efforts to scale require skilled nursing facilities to play a significant role.

Throughout the pandemic, North Carolina has evolved its testing guidance to clinicians and laboratories based on the emerging science and guidance from the CDC, and the State will continue to do so. In short, North Carolina advises that anyone with symptoms of COVID-19 or who thinks they have been exposed, should get tested. Consistently, current testing guidance states that clinicians should conduct or arrange for diagnostic testing for any patient for whom COVID-19 is suspected. The guidance emphasizes the importance of ensuring the following populations have access to testing:

- Anyone with symptoms suggestive of COVID-19;
- Close contacts of known positive cases, regardless of symptoms;
- Anyone at higher risk of exposure or at higher risk for severe disease, if they believe they may have been exposed to COVID-19, whether or not they have symptoms including:
  - Persons who live in or have regular contact with high-risk settings (e.g., long-term care facility, homeless shelter, correctional facility, migrant farmworker camp);
  - Persons who are at high risk of severe illness (e.g., people over 65 years of age, people of any age with underlying health conditions[1]);
  - Persons who are members of historically marginalized populations, including those living in geographies with limited testing availability;
  - Healthcare workers or first responders (e.g. EMS, law enforcement, fire department, military); and
  - Front-line and essential workers (grocery store clerks, gas station attendants, construction workers etc.) in settings where social distancing is difficult to maintain.
- Testing should be considered for people who have attended protests, rallies, or other mass gatherings who could have been exposed to someone with COVID-19 or could have exposed others.

In addition to the Department directed testing efforts, other entities are conducting their own testing, including employers, universities, and health systems. For example, many hospitals and clinicians are testing patients when they are hospitalized for non-COVID-related diagnoses or are undergoing a surgical procedure. The Department is closely tracking and collaborating with these entities, not only to track the results of those testing efforts, but because these other testing strategies have North Carolina-wide implications for the supply chain and availability of laboratory resources.

Given the sustained nature of the pandemic, North Carolina is committed to working with federal and local partners to increase testing over a longer period of time with a focus on community-led testing, testing to support K-12 schools that are providing in-person instruction, and proactive surveillance at Institutes for Higher Education.

2. Diversify testing modalities

To date, North Carolina's testing strategy has primarily focused on use of molecular/polymerase chain reaction (PCR) tests, which detect the virus's genetic material. Given the volatile nature of supply chains, demands for testing, and differing testing purposes (e.g., screening asymptomatic and diagnosing symptomatic people), North Carolina is aggressively pursuing emerging testing modalities

[1] CDC's list of health conditions of greatest risk can be found here: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

and approaches to increase the state's testing capacity and efficiency, including use of point-of-care (POC) molecular testing, antigen testing, and pooled testing, as appropriate across the population.

Recognizing the limitations associated with each of these testing modalities, North Carolina developed preliminary recommendations for use, considering testing availability, disease prevalence, and testing periodicity. The Department recently revised its guidance regarding appropriate use of antigen testing, and guidance for reporting results is available on the healthcare guidance section of the NC DHHS COVID-19 website. In August, North Carolina joined several other states in a multistate consortium convened by Maryland Governor Larry Hogan and the Rockefeller Foundation designed to procure additional antigen tests, and the State is closely monitoring the federal government's inventory and distribution plans for the Abbot BinaxNOW antigen testing.

Table 1 below outlines considerations for various testing modalities. As evidence continues to emerge, North Carolina will refine these recommendations accordingly.

TABLE 1. CONSIDERATIONS IN ESTABLISHING TESTING PRIORITIZATION

Criteria	Tests are meaningfully available *(available, affordable, ~24h turnaround time)*	Tests are not meaningfully available *(few, high cost, and/or long turnaround time)*
Local disease prevalence is high (>5% of tests are positive)	Offer widespread community testing with special outreach to high-risk populations and groups, using lowest-cost, best-performing modality	• Prioritize highest-risk groups (symptomatic/known contacts plus a limited number of very high-risk occupational or other groups). • Use frequent lower-sensitivity testing (antigen or POC molecular) on symptomatic/high-risk populations if PCR testing is in short supply • Use serial or repeated (e.g., weekly) lower-sensitivity testing (antigen or POC molecular) or pooled PCR testing on lower-risk/asymptomatic subpopulations, if they are identified, recognizing that the efficiency of pooling generally decreases as prevalence increases • Emphasize use of non-testing approaches to decrease transmission.
Local disease prevalence is low (<5% of tests are positive)	Use lowest-cost, best-performing modality to quickly identify and address localized outbreaks by testing symptomatic individuals, known/suspected contacts or very high-risk occupations	• Use frequent lower-sensitivity testing (antigen or POC molecular) on symptomatic individuals, known/suspected contacts or very high-risk occupations if PCR testing is in short supply. • Use serial or repeated (e.g., weekly) lower-sensitivity testing (antigen or POC molecular) or pooled testing for ongoing population surveillance or if group testing is desired. • Emphasize use of non-testing approaches to decrease transmission.

3. Build testing capacity

Testing capacity is also dependent on the number of entities able to collect and process specimens in the state. To identify barriers to maximizing use of capacity, the Department surveys the ability of existing partners to expand testing capacity, including primary care and urgent care practices, Federally Qualified Health Centers (FQHC), community health partners, health systems and laboratories.

In addition, the Department continues to procure vendors to add testing capacity and provide test resources to meet the needs of local communities. North Carolina recently selected an additional vendor, Optum Serve, to join two previously selected vendors – the North Carolina Community Health Center Association and StarMed Urgent and Family Care, P.A. – to increase access to testing in the state. Recognizing that COVID-19 highlights and exacerbates persistent health disparities in our communities, the Department is deploying vendors in high priority outbreak areas and to historically marginalized populations through the County Rapid Response and the Community testing in High-priority And Marginalized Populations (CHAMP) initiatives.

4. Leverage public and private funding

Cost should not be a barrier for any North Carolinian to obtain needed testing. Most costs related to testing for detection or diagnosis of COVID-19 should be covered by health insurance programs (Medicare, Medicaid, and private insurance) and the Health Resources & Services Administration (HRSA) COVID-19 Uninsured Program.

As of Sept. 1, 2020, North Carolina Medicaid providers can be reimbursed for COVID-19 testing of uninsured individuals under the NC Medicaid Optional COVID-19 Testing (MCV) program, set up through authority granted by the Families First Coronavirus Response Act (FFCRA) and in effect until there is no longer a COVID-19 declaration of emergency.

Beginning in June 2020, the Department leveraged federal funding to deploy no-cost testing events in hard hit communities across the state and later to fund biweekly staff testing in long-term care facilities through November 2020. The Department also hosts a "Find My Testing Place" tool to help residents identify testing sites in their local area.

It is critical to North Carolina's testing efforts that insurance carriers meet their obligations to cover the cost of testing. In addition, providers and vendors must meet their obligations to appropriately bill for testing services.

In some limited circumstances, such as where testing is purely for surveillance purposes, commercial insurance coverage, and even Medicare and HRSA, may not cover the costs of the tests. North Carolina may draw on federal dollars designated to cover the cost of certain surveillance testing if appropriate.

5. Monitor, learn, and adapt

North Carolina will continue to leverage data across the public and private sectors to track the pandemic, guide policy and operational planning, and inform how testing resources are channeled. Department strategies will likely change over time, not only as the disease progresses, but to address issues in supply chain, new testing modalities or technologies, and field and laboratory capacity.

North Carolina also will continue to engage key partners, including federal, state and local officials, healthcare providers and payers, commercial and hospital laboratories, suppliers of testing and diagnostic equipment, business leaders and employers, community leaders, educational and other public and private institutions, to assess adequacy of this testing approach and adapt it as the science evolves, and new federal guidance and resources become available.