

ELC ENHANCING DETECTION: NORTH CAROLINA TESTING PLAN

2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	North Carolina
Population Size:	10,500,000

1. Describe the overarching testing strategy in your state or jurisdiction.

a) North Carolina’s coordinated testing action plan is a data-driven approach that (1) supports individuals with suspected disease, or individuals who are known or presumed to be exposed, (2) supports frequent assessment of individuals at high risk for infection, and (3) promotes health equity for historically marginalized populations. These goals are based on emerging evidence and best practices outlining how testing frequency and approaches should vary by individual risk profile, as well as external factors such as where people work and reside. North Carolina is in the process of finalizing testing estimates, based on a “bottom-up” approach that models daily testing thresholds based on a range of factors, including: (1) the approximate size of cohorts of interest in prioritized populations, (2) associated risk of infection; (3) risk of adverse health outcomes, (4) disease prevalence, and (5) public health and economic goals for testing. COVID-19 testing needs may evolve in late summer and fall as schools and universities reopen, more individuals return to work, and flu season begins. For June and July, we have preliminarily identified a group of individuals who should be high priority for testing. Some may require testing only once (e.g., individuals who present with acute symptoms) while other individuals may require repeated testing (e.g., individuals who live or work in high-risk environments). Altogether, the group could account for as many as 40,000-60,000 tests per day. As we refine our strategy, additional federal financial and resource supports are needed to achieve increased testing goals.

While a decentralized public health system, the NC Department of Health and Human Services (NC DHHS) has engaged in several efforts to increase SARS-CoV-2 testing. NC DHHS has strengthened coordination and partnership among Local Health Departments, Federally Qualified Health Centers (FQHCs), healthcare systems, healthcare providers, community groups, commercial laboratories, and hospital laboratories to unlock current testing capacity by helping collection sites ramp up to maximum capacity; cataloging the existing ecosystem of collection sites, created new collection sites to increase daily testing numbers, and using data to inform how to deploy testing.

Additionally, NC DHHS has a Test Surge Workgroup to develop a coordinated action plan to increase testing throughput and capacity, expand testing sites, diversify testing options (including antibody, antigen, and pooled testing), and address risks associated with testing supplies and PPE availability. This workgroup brings together a diverse group of stakeholders—many representing the aforementioned partners above—to increase transparency around current testing capabilities of laboratory, clinical, and retail partners and ensure continued progress on increasing COVID-19 testing in North Carolina.

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The State is using informational resources provided by the White House Coronavirus Task Force and diagnostic test and instrument manufacturers to identify clinical laboratories in North Carolina with low throughput testing platforms (e.g., Cepheid GeneXpert and Becton Dickinson BD Max), medium throughput platforms (e.g., ThermoFisher 7500 and Hologic Panther) and high throughput platforms (e.g., Roche Cobas and Cepheid Infinity). These laboratories are surveyed to assess their capability and capacity to test for SARS-CoV-2. The survey evaluates the availability of collection supplies, testing reagents, and adequate staffing. Data from these surveys will be used to support the technical and data infrastructure needed (command center approach, described later), to direct resources and identify opportunities for rapid response to surge testing needs.

NC DHHS is also accessing multiple new paths to meet increased demands for testing. As additional platforms and methods receive emergency use authorizations (EUA) from the Food and Drug Administration (FDA), locations with these instruments are identified and surveyed. These new methods include traditional laboratory-based molecular tests as well as new approaches, such as point-of-care molecular testing, antigen detection, and pooled testing methods.

b) NC DHHS testing strategy provides testing at many locations, including non-traditional laboratory sites. NC DHHS has identified more than 500 testing sites in rural and urban areas of the state, and has started to deploy “pop-up” testing sites to meet urgent demand. The sites are publicly listed on the DHHS website, including an interactive “Find My Testing Location” feature to allow residents to search by zip code for testing sites. For each type of site, NC DHHS has developed a high-level set of criteria to inform vendor engagement and drive effective and efficient testing expansion.

NC DHHS released a request for qualifications (RFQ) to identify vendors qualified to perform testing for COVID-19 including High throughput testing, Directed/Mobile testing, and Laboratory Reserve Capacity. For high throughput testing sites (>100 tests per site per day), NC DHHS has selected vendors who bring the most full-service test collection offering to alleviate supply, labor, and infrastructure challenges in the short term and as part of surge testing. These locations include brick and mortar retail stores and pop-up/drive-thru settings. Low throughput locations (<50 tests per site) include pharmacies, described below, and community settings capable of performing point-of-care testing and specimen collection to bring the most cost-effective and low investment to the State by providing testing coverage to areas that are not covered by the range of current or planned facilities.

A “Strike team” model is being pursued to rapidly deploy resources to address an acute need for testing in facilities with outbreaks, and mobile solutions will address gaps in testing capacity by delivering tests to specific underserved areas. Vendors for these models will be able to effectively handle the logistics of site identification and coordination as well as partner with trusted members of the community.

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Also, NC DHHS has partnered with Walmart, Walgreens, and CVS for testing at multiple locations across the State. Walmart and Walgreens are part of the federal Health and Human Services (HHS) partnership for testing across the United States. CVS is expanding its corporate testing initiative and opening 55 new SARS-CoV-2 testing sites at select CVS Pharmacy drive-thru locations in North Carolina. Each CVS site manages their scheduling and reporting.

NC DHHS is also working with external pharmacy associations to help make the connection for independent pharmacies to partner with Local Health Departments to initiate testing.

c) Currently, the North Carolina State Laboratory of Public Health (NCSLPH), commercial laboratories, and hospital laboratories around the State are validating and implementing serology testing. The NCDHHS Test Surge Workgroup's Scientific Advisory Council recently finalized interim recommendations for the use of serology testing in the State. These recommendations include:

1. Antibody testing for SARS-CoV-2 should not be used as a first-line diagnostic test in patients who have had an onset of COVID-19 symptoms within the past 7 days.
2. In the face of long-standing symptoms of COVID-19 (defined as greater than 14 days), antibody testing may be used as one piece of evidence in the confirmation of infection with SARS-CoV-2. This can be useful if PCR based testing is negative, showing an absence of detectable virus, or unavailable. It can also be used for individuals who present with possible delayed complications of SARS-CoV-2 infection, such as Multisystem Inflammatory Syndrome in Children.
3. Antibody testing should not be used as an 'immunity voucher' to assure the safety of individuals or create a SARS-CoV-2 free environment.
4. Antibody testing can be used as an epidemiologic tool to approximate the prevalence of previously infected individuals and regularly determine how this prevalence is changing over time. This data can help drive public policy decision-making.

NC DHHS is taking steps to make all positive and negative serology results for North Carolina residents reportable via ELR as of September 1, 2020. This will allow tracking of testing across the state and assessment of percent positivity of tests going forward statewide and within specific demographic groups and geographic areas.

Additional strategy for the use of serology as part of the North Carolina Coordinated Testing Action Plan is being developed based on current ongoing research in our state. NC DHHS is partnering with multiple University collaborators to evaluate the prevalence of symptomatic and asymptomatic infections among North Carolina residents. Lessons learned from these studies, as well as other research efforts will inform modification to the North Carolina Coordinated Testing Action Plan to finalize a strategy for the use of serology testing. Potential uses for the NCSLPH capacity includes screening for convalescent

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plasma donors, testing in skilled nursing facilities, and supporting uninsured or historically marginalized populations.

d) The composition of the Test Surge Workgroup—including Local Health Departments, FQHCs, healthcare systems, healthcare providers, pharmacies, community groups, academic partners, health information technology, commercial laboratories, and hospital laboratories—is designed to assure communication of the State’s approach to expanded testing and coordinate a response across stakeholder groups. Workgroup meetings are used to review progress toward the State’s expanded testing goals, communicate success stories and best practices, and identify barriers and potential solutions.

NC DHHS also developed a Personal Protective Equipment (PPE) and Collection/Testing Supply Command Center model to bring together testing, contact tracing, historically marginalized populations, data, and communications functions into a central command center. This command center will enable an “air traffic control” view between the State and Local Health Departments and inform the tactical strategy. The command center team with operational, program design and implementation, and technical skills, including ad hoc data analysis and analytics, will support the coordination of complex logistics across the strategy to assure partners have the resources to achieve the State’s testing goals. This model connects supply with demand and enables communications to be directionally correct.

Weekly assessments (surveys) of local health partners, clinical laboratories, and providers informs proactive strategies to support the maintenance of human resources and supply inventories. The PPE and Supply Command Center is implementing a process to proactively monitor requests for PPE, collection, and testing supply resources. Current guidance permits requests for a 7-day supply of PPE and supplies (from both State and federal warehouse). The command center model also facilitates and oversees the delivery of PPE and supplies. As part of the request process, the command center will facilitate reporting on PPE shortages, project and monitor the burn rate for collection kits and testing supplies, and address emerging concerns. With continued challenges obtaining PPE, collection supplies, and testing reagents; the State will need ongoing federal support to achieve our expanded testing goals. This structure will also use data to inform laboratory capacity expansion decisions.

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Table #1a: Number of individuals planned to be tested, by month

BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Diagnostics*	210,000	300,000	500,000	600,000	720,000	864,000	1,040,000	1,250,000	5,484,000
Serology			10,000	23,000	36,000	50,000	70,000	100,000	289,000
TOTAL	210,000	300,000	510,000	623,000	756,000	914,000	1,110,000	1,350,000	

*Each jurisdiction is expected to expand testing to reach a minimum of 2% of the jurisdictional population.

Table #1b: Planned expansion of testing jurisdiction-wide

Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic through-put	Daily serologic through-put	Specific at-risk populations targeted (list all)
LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru	Public health lab	State Laboratory of Public Health	1,000	500	Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-	Commercial or private lab	Mako Medical Laboratory	5,000	600	Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized

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Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic through-put	Daily serologic through-put	Specific at-risk populations targeted (list all)
Thru, Urgent Care					populations, and healthcare workers or first responders
LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care, Pharmacy	Commercial or private lab	LabCorp	15,000	5,500	Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Commercial or private lab	Quest Diagnostics	2,000	500	Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Commercial or private lab	Diatherix	1,000		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders

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LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Commercial or private lab	Viracor	500	100	Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Commercial or private lab	AccessDx	100	1,000	Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Commercial or private lab	AIT	800		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
LHD, FQHC, LTCF, Hospital, Healthcare	Commercial or private lab	Aegis	200		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age

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Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic through-put	Daily serologic through-put	Specific at-risk populations targeted (list all)
Provider, Mobile Clinic, Drive-Thru, Urgent Care					with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Commercial or private lab	Bako Diagnostics	2,000		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
Walgreens	Drug store or pharmacy	Walgreens	200		
Eden Drugs, Harris Teeter, Kroger	Drug store or pharmacy	eTrueNorth (Gravity Dx)	200		
Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Hospitals or clinical facility	Wake Forest Baptist Medical Center	300		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders

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Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Hospitals or clinical facility	Duke	1,600	300	Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Hospitals or clinical facility	Moore Regional	15	5	Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Hospitals or clinical facility	Columbus Regional	15		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
Hospital, Healthcare Provider, Mobile	Hospitals or clinical facility	Randolph	10		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age

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Clinic, Drive-Thru, Urgent Care					with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Hospitals or clinical facility	CarolinaEast	250		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Hospitals or clinical facility	New Hanover	100		
Cabarrus-Rowan Community Health Centers	Federally Qualified Health Center	Cabarrus-Rowan	100		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized

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Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Hospitals or clinical facility	Watauga	250		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Hospitals or clinical facility	UNC	2,000	300	Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Hospitals or clinical facility	Novant	2,500		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders

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LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru	Hospitals or clinical facility	Durham VA	800		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
Rural Health Group	Federally Qualified Health Center	Rural Health	70		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Hospitals or clinical facility	WakeMed	900		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
LHD, LTCF, Hospital, Healthcare	Hospitals or clinical facility	Atrium	1,000	2,000	Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age

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Provider, Mobile Clinic, Drive-Thru, Urgent Care					with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
LHD, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Hospitals or clinical facility	Cone	200		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru, Urgent Care	Hospitals or clinical facility	Vidant	1,000	4,800	Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
Henderson County Health Department	Public health lab	Henderson	40		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized

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					populations, and healthcare workers or first responders
Walmart	Drive-thru testing site	eTrueNorth (Healthquest Esoterics)	200		
CVS	Drug store or pharmacy	LabCorp	2,750		
LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru	Commercial or private lab	Aperiomics	20		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru	Commercial or private lab	Clarity Labs	2,500	100	Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders

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LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru	Commercial or private lab	Excelsior Diagnostics	100		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru	Commercial or private lab	GENETWORx	1,000		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru	Commercial or private lab	Integrated Cellular & Molecular Diagnostics	100		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders

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LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru	Commercial or private lab	Next Molecular Analytics	2,000		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru	Commercial or private lab	Poplar Healthcare	3,000		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
LHD, FQHC, LTCF, Hospital, Healthcare Provider, Mobile Clinic, Drive-Thru	Commercial or private lab	Vista Clinical Diagnostics	260	100	Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders
LHD, FQHC, LTCF, Hospital, Healthcare	Commercial or private lab	Kashi Clinical Laboratories	1,000		Persons who live in or have regular contact with high-risk settings, persons who are at high risk of severe illness, people of any age

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Provider, Mobile Clinic, Drive-Thru					with underlying health conditions, persons who come from historically marginalized populations, and healthcare workers or first responders

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2020 Direct Expansion of SARS-COV-2 Testing by Health Departments

2. Describe your public health department's direct impact on testing expansion in your jurisdiction.

a) NC DHHS is expanding testing across the State by contracting with private testing vendors, collaborating with commercial and hospital laboratories, coordinating collection and testing resources for stakeholders (Local Health Departments (LHDs), FQHCs, nursing homes, healthcare systems, and healthcare providers), and expanding capacity at the NCSLPH. A request for qualifications (RFQ) was released to identify vendors qualified to perform testing for COVID-19 including High throughput testing, Directed/Mobile testing, and Laboratory Reserve Capacity.

Ideal vendors will provide resources to support testing site management, specimen collection, human resources, and patient billing. Vendors are also expected to coordinate with the existing healthcare infrastructure. Task orders for specific testing activities (e.g. long-term care facilities) will be issued to the pool of vendors identified by the RFQ.

The decentralized public health system in North Carolina provides unique opportunities and challenges to expanding testing capacity statewide. LHDs are leading the response to COVID-19 in their jurisdictions and coordinating with their stakeholders to expand testing. Some LHDs with clinical laboratories have established testing, and others are working to identify paths to expand testing. These paths may require new equipment, access to testing reagents, and additional staff. LHDs are routinely engaged in rapid outbreak response and many are partnering with their hospital systems, contracting with commercial laboratories, and maximizing the use of non-traditional laboratory options to assure testing for their residents. NC DHHS provides guidance, subject matter expertise, and direct support for LHDs in their efforts to expand testing.

In support of expanded State testing efforts, the NCSLPH is enhancing its existing testing infrastructure, which currently includes a variety of extraction platforms and real-time PCR instrumentation. Capacity expansion and workflow enhancements include the integration of automation via liquid handling instrumentation, utilization of existing multifunctional platforms, procurement of multiple high-throughput platform systems, and incorporation of fully integrated rapid molecular testing platforms.

b) Promoting health equity for historically marginalized populations is a foundational goal of North Carolina's Coordinated Testing Action Plan. NC DHHS assembled workgroups around historically marginalized communities and vulnerable populations to assess and develop strategies to respond to the needs of these groups. In addition, NC DHHS guidance to providers and laboratories stated that clinicians should ensure testing for these populations.

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The historically marginalized and vulnerable population workgroups have identified goals and is focused on actioning numerous tactics within each goal:

1. Effectively reach the population to provide COVID related education and guidance.
2. Connect people to medical and behavioral care providers regardless of ability to pay.
3. Link people to needed resources to address social determinants of health.
4. Protect essential, undocumented and front-line workers from exposure to COVID

The NC DHHS Historically Marginalized Population workstream recognized that a disproportionate share of resources needed to be directed to these populations to combat long standing health disparities. An initiative, CHAMP (Community (testing in) High-priority And Marginalized Populations, performed an analysis of the State with a focus on three different historically marginalized populations, American Indian, African American and LatinX. Using population density and added filters unique to each population (i.e. age and chronic disease in the AA population or construction and farm jobs in LatinX), zip codes were identified across the state as being high priority. NC DHHS issued a task order for high throughput testing vendors to reach these zip codes to offer increased access to free testing. Specific requirements in the task order, unique to the HMP, requires that awarded vendors partner with community partners and county leaders, provide culturally and linguistically appropriate services, employ staff that resembles the population, and provides a linkage to medical home. A “Secret Shopper” program has been launched to use trained DHHS staff to attend events to measure their performance on some of the contractual requirements.

The Department is also committed to ensuring all patients and staff in skilled nursing facilities, and other long-term care facilities, are tested. On June 30, 2020, NC DHHS announced a partnership with Omnicare to make one-time facility-wide testing available to residents and staff in all North Carolina skilled nursing facilities. CVS Health will bill insurance for this one-time testing to the extent possible, and the Department will cover any additional costs for testing.

NC DHHS is evaluating recommendations for testing in adult or family care homes, ICF-IIDs, residential mental health facilities, correctional facilities, homeless shelters, meat packing plants, and farms. The Department will continue to work with stakeholders to assure ramped up capacity to enable testing of individuals in these cohorts. Bringing these efforts to scale will require insurance carriers and self-insurance plans to play a significant role.

c) Several barriers have been identified with increasing testing capacity. A significant amount of additional laboratory capacity, testing supplies, and PPE will be needed to support our testing strategy. Additionally, there is uncertainty on the extent to which payers will cover testing for those without a doctor’s order, testing that is strictly for surveillance purposes, periodic testing if they do not share North Carolina’s assessment of optimal testing interval or underlying risk, and insufficient funding to

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support the uninsured and underinsured. An increase in testing will also increase the need to provide support for COVID positive patients to safely quarantine; a strategy will be needed to identify supports, how target populations access supports, and how to cover the costs of these services.

To mitigate these barriers to the best extent, NC DHHS is using informational resources provided by the White House Coronavirus Task Force and diagnostic test and instrument manufacturers to identify clinical laboratories in North Carolina with diverse instrument platforms. These laboratories are surveyed routinely by NC DHHS to assess their capability and capacity to test for SARS-CoV-2. Data from these surveys is fed into a command center to direct resources, minimize barriers to testing, and maximize utilization of available capacity.

In response to collection supply challenges, NC DHHS has implemented a process for providers around the State to request resources. NC DHHS is distributing collection supplies allocated by the FEMA, as well as those procured on the commercial market, to LHDs, FQHCs, healthcare providers, and community organizations performing specimen collection activities to support expanded testing.

The Test Surge Workgroup meets weekly to review progress toward the State's expanded testing goals, communicate success stories, best practices, and identify barriers to testing and develop solutions. Moreover, the workgroup's Scientific Study Council is accessing multiple new methods to meet increased demands for testing and navigate supply-chain challenges. These new methods include traditional laboratory-based molecular tests as well as new approaches, such as antigen detection and pooled testing methods.

To assure use of existing testing capacity, NC DHHS has developed a robust statewide communication plan and an interactive website listing all specimen collection site in the State. Residents can search for the site nearest to their address and learn more about the requirements for testing, including appointment requirements and contact information for the site.

Finally, to strengthen our data infrastructure and streamline submission of specimens and reporting results, NCSLPH is implementing an Electronic Test Ordering and Reporting (ETOR) system. Additionally, the NC DHHS Epidemiology Section is working with clinical laboratories to expand electronic laboratory reporting (ELR) to the North Carolina Electronic Disease Surveillance System (NCEDSS). The expansion of ELR into NCEDSS will maximize clinical laboratory reporting efficiency into the public health system.

d) A strategy for the use of serology as part of the North Carolina Coordinated Testing Action Plan is still being developed. As the prevalence of North Carolina residents with antibodies and the relationship between antibodies to SARS-CoV-2 and immunity to future infection remains unknown, NC DHHS is partnering with multiple University collaborators to evaluate this relationship. Lessons learned from

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these studies, as well as, other research efforts will inform modification to the North Carolina Coordinated Testing Action Plan to finalize a strategy for use of serology testing. Currently, the NCSLPH is in the process of implementing serology testing on the laboratory's high-throughput serological instruments (Abbott Architect and DiaSorin LIAISON XL). As the statewide strategy is finalized, the NCSLPH serological testing capacity will be utilized in support of those testing goals.

e) North Carolina's vision for a data-driven testing and contact tracing strategy demands coordination with private and public partners to increase testing capacity, expand testing sites, promote and encourage people to get tested, work with the federal government and private partners to address supply limitations, and provide timely relevant data to public health experts and medical providers in a secure manner. To best determine when to modify social distancing, testing, tracing, and other mitigation strategies, NC DHHS will leverage North Carolina's comprehensive, public-facing dashboard featuring a standardized set of measures across our state and key performance indicators to track progress. Since June, NC DHHS has been working with 9 counties that were identified internally and by federal partners as areas for concern based on the increasing trajectory of cases. A team has been working with these counties to deploy resources, including staff and testing assets. Internally, NC DHHS has also developed a series of metrics including elevated incidence of cases, lowest testing per capita, percent positivity, growth in cases over 65 years old, and fastest growth in historically marginalized populations that are used in combination to prioritize additional counties support. The Department will continue to analyze new data, including COVID-19 surveillance data, hospitalizations, availability of protective equipment and other supplies, and hospital capacity.

The Department intends to phase in a testing approach over a period of two to three months, allowing time to further increase testing capacity. Individuals with COVID-19 symptoms or who have been in contact with someone who has tested positive for COVID-19 and populations in skilled nursing facilities will be tested first, with repeat testing for skilled nursing facilities and additional populations phased in as additional testing becomes available. Testing progress will be assessed based on measures of infrastructure, equity, and reach. Current testing metrics focus on reach, including the number of testing sites at the state and county level, the number of diagnostic tests performed and reported, and the proportion of tests with positive results. Future assessments may evaluate the distribution of tests by the county of residence and race/ethnicity of the individual being tested.

Test estimates assume that North Carolina's testing needs remain relatively constant or increase at a sustainable rate, including holding constant the periodicity of testing for certain populations. Depending on observed trends, test frequency for certain populations may increase or decrease. It is also possible that, as the state relaxes restrictions, testing needs could rise more steeply than planned if individuals and organizations are not able to adhere to common prevention measures in order to mitigate community-level transmission. As mentioned previously, North Carolina has selected a pool of pre-qualified vendors as part of a competitive "Request for Qualifications" that will support increased testing capacity and flexibility.

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f) Governor Roy Cooper's Executive Order 116 provided certain procurement flexibilities to the State Agencies, including a waiver of the requirement to post procurement opportunities publicly and the ability to use a single source vendor based on urgency.

In terms of acquiring testing materials, NC DHHS Office of Procurement, Contracts, and Grants has developed the following procedures:

- a. Vendor vetting process for use by the sourcing team to readily identify available vendors who can supply needed materials.
- b. Developed a Web-based form allowing vendors to submit current availability of PPE and other materials.
- c. Stood up a sourcing team which can rapidly identify vendors, obtain quotes and, via the Emergency Operations Center, issue purchase orders.
- d. Establish qualified vendor pools for laboratory testing and contact tracing through an RFQ process to further enhance our testing capacity through contract methods.

For permanent positions identified as COVID-19 critical, NC DHHS has a Human Resources Rapid Response Team that assists the Department's Divisions in sourcing candidates along with other recruitment strategies to find candidates, vet them, and forward these individuals to local offices. In addition to hiring permanent positions, NC DHHS works with a temporary staffing services agency to provide rapid identification and on-boarding of staff needed to fill short-term needs for the pandemic response.

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Table #2: Planned expansion of testing driven by public health departments

BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Number of additional* staff to meet planned testing levels	2	4	4	8	2	0	0	0	20
FOR DIAGNOSTIC TESTING									
How many additional* testing equipment/ devices are needed to meet planned testing levels? (provide an estimated number, and include platform details in narrative above)	0	2	0	2	4	0	0	0	8

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BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Volume of additional swabs needed to meet planned testing levels ⁺⁺	0	0	450,000	600,000	720,000	864,000	1,040,000	1,250,000	4,924,000
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels ⁺⁺	0	75,000	450,000	600,000	720,000	864,000	1,040,000	1,250,000	4,999,000

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BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher)	0	0	1200/day ThermoFisher	1200/day ThermoFisher; 300/day Hologic Panther	1200/day ThermoFisher; 800/day Hologic Panther	1200/day ThermoFisher or CDC multiplex; 800/day Hologic Panther	1200/day ThermoFisher or CDC multiplex; 800/day Hologic Panther	1200/day ThermoFisher or CDC multiplex; 800/day Hologic Panther	0
FOR SEROLOGIC TESTING									
Number of additional* equipment and devices to meet planned testing levels	0	0	2	0	0	0	0	0	2

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BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher)	0	0	0	100/day Abbott Architect; 100/day DiaSorin Liason XL	100/day Abbott Architect; 100/day DiaSorin Liason XL	100/day Abbott Architect; 100/day DiaSorin Liason XL	100/day Abbott Architect; 100/day DiaSorin Liason XL	100/day Abbott Architect; 100/day DiaSorin Liason XL	0

* Report new monthly additions only, not cumulative levels

++ For May and June, only include needs beyond the supplies provided by FEMA. Report new monthly additions only, not cumulative levels.