

ELC ENHANCING DETECTION: TENNESSEE TESTING PLAN

2020 Overarching Jurisdictional SARS-CoV-2 Testing Strategy

Jurisdiction:	Tennessee
Population Size:	

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

a)The Tennessee Department of Health (TDH) has a comprehensive plan for broad and widely available COVID-19 testing in the population. Thus far we have exceeded the goal of 2% on a monthly basis. Core public health surveillance activities will be the foundation of our testing approach. The TDH State Public Health Laboratory (SPHL) was the first laboratory in the state to conduct COVID-19 testing which was validated and approved by CDC. The SPHL detected the first case in a traveler who attended an international meeting and has increased capacity dramatically since the pandemic has taken hold in Tennessee. The TDH strategy and testing plan focuses on near-term needs and longer term through the end of calendar year 2020. The testing plan addresses all topics in detail below.

a)The TDH SPHL has rapidly scaled testing capacity throughout the COVID-19 pandemic. As mentioned, TN was one of the first states to successfully validate the CDC SARS-CoV-2 PCR assay; and from March 2020 until May 2020, the SPHL has increased its testing capacity to 6,000 samples per day (assuming three shifts are running on all platforms with no supply chain interruptions). The SPHL currently utilizes the Panther SARS-CoV-2 assay (6 instruments), Thermofisher TaqPath (4 KingFisher extractors & 12 ABI 7500s), and Cepheid GenXpert (2 Infinity48 instruments & 1 four-unit module) to allow for high throughput testing for SARS-CoV-2 within the jurisdiction. Cepheid GenXpert are utilized for rapid resulting. To further increase capacity, the SPHL is implementing pooled testing for asymptomatic individuals and will be adding the CDC influenza SARS-CoV-2 multiplex assay in anticipation of the upcoming influenza season. At the SPHL, a laboratory web portal is being built to facilitate electronic ordering of tests and results back to the submitter to reduce pre- and post- analytic bottlenecks and reduce turnaround time. In addition to testing at the SPHL, TDH has partnered with multiple private commercial laboratories who do high throughput testing to test samples collected routinely at local health departments and for surge / targeted testing events of high-risk or other populations or for outbreak response. The TDH SPHL has also assisted multiple commercial and academic laboratories to assess and ensure reliable and accurate testing. These efforts have and will continue to include retesting from laboratories which are newly operating to provide COVID-19 testing in the marketplace. Validating results will remain as a critical function for the TDH SPHL. TN has worked rapidly to expand its workforce supporting COVID-19 activities. State-wide hiring exemptions have been made for positions supporting COVID-19 in efforts to expedite the hiring processes, and temporary employment services are being utilized in order to quickly onboard new staff to support the COVID response. Standard state procurement processes have been circumvented in order to provide the appropriate resources in the most expediate manner. TDH has been able to rapidly onboard commercial laboratories as approved vendors to conduct testing on behalf of the state. Testing capacity has been greatly enhanced through these vendor relationships facilitating large-scale testing in correctional facilities, long-term care facilities, testing at Health Department drive-through Remote Assessment Sites, and many other outbreak or clusters. Relationships have been fostered with urban housing groups, minority populations,

ELC ENHANCING DETECTION: TENNESSEE TESTING PLAN

and other community-based organizations to facilitate testing and plan future events. TDH has private-public partnerships planned to further enhance testing of our most vulnerable elderly populations and healthcare communities. These efforts involve testing capacity being made available by TDH. The TDH testing plan will support population needs directly with the SPHL and vendor relationships throughout 2020 as commercial laboratory capacity continues to grow. A transition back to the normal medical healthcare delivery paradigm is anticipated to occur during this time and into 2021 but it is dependent of the trajectory of COVID-19. TDH is committed to directly expanding and maintaining testing capacity to meet the surveillance and response needs in our population for as long as it is needed.

b)TN has performed substantial outreach in order to provide testing at a variety of locations and for a variety of populations. The Unified Command Group has made testing of vulnerable populations including the elderly a top priority. Since mid-April testing at all 89 rural TN health departments has been available free of charge and for any person seeking testing, regardless of symptoms or high-risk contact. No cost drive-through testing at Remote Assessment sites has made testing more widely available to low socio-economic segments of our population. The Remote Assessment sites routinely process 40,000 specimens for testing on a weekly basis across state. In the month of April, surge testing events were advertised to the general population statewide on three weekends. The sampling was conducted in collaboration with the National Guard. During these events approximately 25,000 tests were performed. This approach was successful in facilitating testing for many underserved populations and will be considered later in 2020. In addition, TN has completed mass testing in: all (~700) long term care facilities, all staff and inmates in all state-run correctional facilities (~26,500), testing of all staff and residents of state-run or contracted Department of Intellectual & Developmental Disabilities group homes, testing of all staff and residents in 3 state-operated Regional Mental Health Institutes, testing in public housing communities in Nashville, Chattanooga, Knoxville and Memphis, high-risk children under the supervision and care of the Department of Children's Services. Continual and expanded outreach efforts are underway. Retesting plans include response to outbreaks and serial testing of staff in Nursing Homes on a weekly basis. Planning with residential medical facilities has included options for point-of-care testing to facilitate rapid turnaround time. For nontraditional sites, staff (public health staff or TN National Guard) are deployed to the location for collection if that support is needed. Based on the region of the state where the collection occurs, samples will then be triaged to the appropriate laboratory for testing. TDH has experienced a large increase in COVID-19 among Hispanic groups including migrant workers and pregnant women. TDH has conducting community outreach to encourage testing of women of child-bearing age and has collaborated closely with the Latinx community to promote testing messaging in both English and Spanish. We have also conducted large focused testing events in response to outbreaks among critical infrastructure workers. This is a fundamental part of our testing plans to rapidly identify, isolate cases, and quarantine contacts throughout the remainder of 2020. Other novel private-public partnerships are being evaluated including testing at pharmacies. Both Walgreens and CVS have been in contact with TDH about testing plans and locations. Testing plans will include other non-traditional testing sites and collaboration with the SPHL to rapidly facilitate testing from sampling sites.

ELC ENHANCING DETECTION: TENNESSEE TESTING PLAN

c)The TDH State Public Health Laboratory has validated serology testing for SARS-CoV-2 and started testing for specific populations. We are using the Abbott architect platform. Serology testing strategies have been implemented with State Academic Medical Centers. Nearly 12,000 serological tests have been performed. Based on these pilot data, serological testing will be considered broadly for frontline healthcare workers and then expanded into at risk populations if appropriate. As more information and guidance around serological testing becomes available, informed strategies and decisions will be made. TDH considers serology to have potential value but current knowledge is lacking on the interpretation regarding seropositivity and durable immunity. Data indicates that most COVID-19 cases seroconvert. TDH will follow CDC guidance regarding screening for past infection.

d)The Unified Command Group is comprised of the Department of Military, Tennessee Emergency Management Agency, and TDH. The operating plan is an incident command system structure under the leadership of Governor Bill Lee. The majority of logistical support is handled by the TN Emergency Management Agency (TEMA), including procuring and distributing PPE and procuring and distributing laboratory reagents/materials (under the guidance of SPHL leadership). Within the Health Department, daily email communications between the Laboratory and Epidemiology occur regarding testing capacity, reagent and specimen collection kit inventory. Inventories of all needed supplies are closely tracked throughout every day and needs are communicated with partners. TDH maintains close working relationships with hospital partners. Relationships exist through the Hospital Preparedness program and Healthcare Coalitions. Additionally, the SPHL maintains close relationships with commercial laboratories regarding existing capacity. We are a mixed model public health jurisdiction and correspond daily with state and city-county run health departments. Through our State Health Operations Logistics team we will regularly assess test kit availability and staffing needs of all partners being responsive to their varying testing needs.

ELC ENHANCING DETECTION: TENNESSEE TESTING PLAN

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*	225,000	250,000							475,000
Serology		12,000							12,000
TOTAL	225,000	262,000							

*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)
TN State Public Health Lab-Nashville	Public health lab		2,500	500	
TN State Public Health Lab-Knoxville	Public health lab		650	300	
AEL	Commercial or private lab		5,000	900	
PathGroup	Commercial or private lab		10,000	2,000	

ELC ENHANCING DETECTION: TENNESSEE TESTING PLAN

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)
Genetic Assays	Commercial or private lab		130		
Poplar Healthcare	Hospitals or clinical facility		2,000		
St. Jude	Hospitals or clinical facility		500		
Vanderbilt University Medical Center	Hospitals or clinical facility		350		
Compass Laboratory Services	Commercial or private lab		500		
Highlands Pathology	Hospitals or clinical facility		12		
Diatherix	Commercial or private lab		5,200		
Quest	Commercial or private lab		8,500		
Resolve MDx	Commercial or private lab		1,500		

ELC ENHANCING DETECTION: TENNESSEE TESTING PLAN

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)The TN Department of Health has worked to rapidly expand testing capacity throughout the COVID-19 pandemic. TN was one of the first states to successfully validate the CDC SARS-CoV-2 PCR assay; and from March 2020 until May 2020, the TN SPHL has increased its testing capacity to 6,000 samples per day (assuming three shifts are running on all platforms with no supply chain interruptions). SPHL has considered increased staffing to include 2nd, 3rd, and weekend shifts in order for the laboratory to drastically increase testing capacity; however, state hiring freezes and inability to recruit additional scientists utilizing temporary agencies has prevented this from being implemented. SPHL will continue to recruit staff through contractual mechanisms. Request for funding for additional equipment is being made to contribute to enhanced laboratory capacity (3 Abbott Architects, two Hologic Panthers, 1 ABI 7500, 2 King Fisher extractors). TDH is currently using two SPHL locations for COVID-19 testing. Laboratories in Nashville and Knoxville are operating daily. Expansion of capacity in both locations is planned to more rapidly serve population testing.

In addition to testing at the SPHL, TDH has partnered with multiple private commercial laboratories who do high throughput testing to test samples collected routinely at local health departments and for surge / targeted testing events of high-risk or other populations or for outbreak response. Commercial laboratory vendor agreements have been rapidly approved by our fiscal and administrative group to increase capacity in Tennessee. Since mid-April 2020, COVID-19 specimen collection has been offered free of charge in Tennessee's 89 rural counties; TDH's remote assessment sites routinely process 40,000 specimens for testing on a weekly basis and are routinely sent to three commercial laboratories. TDH has also partnered with 22 laboratories that have been authorized for reimbursement by the state for enhanced testing initiatives in long-term care facilities, including mass testing and weekly testing of their staff. TDH has established contracts with laboratories that offer nasal and saliva collection options, which will offer increased capacity for up to 300,000 additional tests/month. TDH has also procured 30 Quidel analyzers for use with the EUA-approved Sofia SARS Antigen Fluorescent Immunoassay (FIA); 10 have been distributed and 20 have been requested and allocated to various partners across the state. TDH will continue to diversify the laboratories being utilized for testing and has identified designated staff members to ensure diversification.

b)The Unified Command Group has been convening a Vulnerable Populations Taskforce. TN has performed substantial outreach in order to provide testing at a variety of locations and for a variety of populations. Since mid-April testing at all 89 rural TN health departments has been available free of charge and for any person seeking testing, regardless of symptoms or high-risk contact. In addition, TN is performing proactive outreach testing in many high-risk communities, regardless of symptoms. To date, TDH has tested all residents and staff in all long-term care facilities in Tennessee (n~700) and has begun mandated weekly testing of Nursing Home staff. Through the mass testing initiative, 77,707 residents and staff were tested. We have tested all staff and inmates in all state-run correctional facilities

ELC ENHANCING DETECTION: TENNESSEE TESTING PLAN

(~26,500) and continue to follow up on new cases and outbreaks. TDH partnered with the Tennessee Corrections Institute to offer voluntary testing in jails, which resulted in testing at 21 facilities (5,486 tests). TDH has tested and continues to pursue:

- testing of all staff and residents in state-run or contracted Department of Intellectual & Developmental Disabilities group homes (68 facilities, 11,345 tests)
- testing all staff and residents in 4 state-operated Regional Mental Health Institutes (3 facilities, 311 tests)
- testing in public housing communities in Nashville, Chattanooga, Knoxville and Memphis (23 events, 12,257 tests)
- testing high-risk children under the supervision and care of the Department of Children's Services (3 facilities, 170 tests)
- testing of Tennessee Highway Patrol staff (8 events, 631 staff)

Multiple other outreach efforts are underway and will continue throughout 2020. Tennessee launched an Economic Recovery Group, which has been offering testing to businesses with >250 employees to encourage return to work. To date, 11 business testing events have been planned or completed. In addition, the TDH Office of Minority Health and Disparities Elimination (OMHDE) launched a Statewide Health Disparities Task Force in April 2020 to address the disparities associated with COVID-19. The Task Force aims to improve the efficiency and effectiveness of disseminating information to communities across the state, as well as examine existing data, monitor trends, and hear from those living, working and serving communities in TN to generate responsive solutions and policies to reduce these disparities. TDH and UCG members participate in both Task Force groups and include community and faith-based partners, academia, health care providers and public health officials. These Task Force groups are meeting weekly by webinar and has addressed critical topics such as TN-specific data trends, data confidentiality and access to testing. For any testing at nontraditional sites, staff (public health staff or TN National Guard) are deployed to the location for collection if that support is needed. Based on the region of the state where the collection occurs, samples will then be triaged to the appropriate laboratory for testing (SPHL or contract laboratory partner). We are working to facilitate homeless testing and continue to conduct outreach to ethnic and racial minorities. Planning is underway to offer testing to approximately 12,000 Kurdish people in middle Tennessee. Outreach to specific populations is planned for the summer and fall and will utilize vendor testing or SPHL capacity. TDH has been planning to increase testing availability with the Tennessee Hospital Association for healthcare workers. Several facilities are testing staff already and have shared their strategy with TDH. We anticipate broadly offering hospitals support for testing of healthcare workers directly involved in patient care. TDH will facilitate this testing at the SPHL or through commercial laboratory vendors, or onsite testing options provided through TDH. TDH SPHL has discussed pooling as a mechanism to create efficiencies in low-prevalence populations.

c)At the SPHL, barriers to efficient testing include data entry bottlenecks associated with manual entry of patient demographics for test accessioning and manual result entry into the SPHL Laboratory Information Management System. Funding has been requested for an Informatics Analyst to perform

ELC ENHANCING DETECTION: TENNESSEE TESTING PLAN

instrument interfacing and improve these workflows. The SHPL is working with APHL and iConnect to implement a Lab Web Portal for electronic ordering and resulting. Additional staffing has been requested to handle data entry for test accessioning. We have been and will continue to coordinate testing activities to maintain a high throughput at the SPHL. We have multiple platforms currently to provide redundancy in testing capability avoiding supply chain issues which might impact a particular platform. Additionally, to mitigate supply chain issues with swabs and media, the SPHL has assembled swab kits in-house. We are using all available assets to mitigate the impact of the supply chain problems. We have had preliminary discussion with the Animal Disease Diagnostic laboratory to assist with swab and media prep. Electronic Laboratory Reporting is one mechanism we will continue to use to streamline reporting to TDH and CDC. TDH reports 100% of information requested by CDC. Feedback has been directed to CDC where duplicate data requests and transmission is requested by different CDC programs. Laboratories unable to submit data via ELR require data processing and manual data entry. TDH has hired additional staff and is recruiting more personnel to assist with the increased reporting burden. Data quality and rapid transmission are critical aspects of increased testing capacity. TDH is also exploring vendors and options for the creation of a laboratory patient portal to improve the ability for patients to quickly access their results from the SPHL.

d)The TDH SPHL has validated serology (IgG) testing for SARS-CoV-2 and began testing for specific populations. Testing is performed on the Abbott Architect i1000 and i2000 platforms in both the Nashville Central Laboratory and the Knoxville Regional Laboratory. A pilot study has tested nearly 12,000 Academic Medical Center staff. The ongoing serology testing strategy is being formulated and will potentially begin with testing of frontline healthcare workers and then expand into at risk populations, eg, Nursing Home staff. As more information and guidance around serological testing becomes available, informed decisions will be made. TDH will follow CDC guidance regarding screening for past infection.

e)Resources and asset availability are closely monitored by the TEMA Logistics and Operations Unit and the TDH Logistics team. Within TDH, daily capacity reports are maintained and shared between laboratory and epidemiology partners regarding collection kits (VTM, Aptima, etc.), PPE, PC, and serology testing capacity. At this time, sentinel surveillance is being conducted through healthcare partners that participate in the Influenza Sentinel Provider Network (SPN). Specimens submitted to the TN SPHL for influenza testing are also being tested for COVID-19. We plan to continue these efforts indefinitely to augment our routine and enhanced surveillance activities. The TDH surveillance team reviews data daily for aberrations. Clusters of cases are investigated to identify at-risk populations and take rapid public health action. Our data team analyzes reports for demographic, facility-level, temporal, and spatial clustering. Epidemiological signals indicating transmission of COVID-19 in vulnerable populations are investigated by state and local health department officials.

f)State-wide hiring exemptions had been made for positions supporting COVID-19 in efforts to expedite the hiring processes, and temporary employment services are being utilized in order to quickly onboard new staff to support the COVID response. To date, approximately 400 new contracted staff have been

ELC ENHANCING DETECTION: TENNESSEE TESTING PLAN

onboarded to support the COVID-19 response in Tennessee. Onboarding will continue throughout the summer. Standard state procurement processes have been circumvented in order to provide the appropriate resources in the most expediate manner. TDH is working collaboratively with state General Services and TEMA to expedite procurement of all materials needed to operationalize the state testing plan.

ELC ENHANCING DETECTION: TENNESSEE TESTING PLAN

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	5	4	2	2	2	2	1	1	19
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)	2	1	2	0	0	0	0	0	5

ELC ENHANCING DETECTION: TENNESSEE TESTING PLAN

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 ⁺⁺	200,000	200,000	200,000	200,000	200,000	200,000	200,000	200,000	1,600,000
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels ⁺⁺	200,000	200,000	200,000	200,000	200,000	200,000	200,000	200,000	1,600,000

ELC ENHANCING DETECTION: TENNESSEE TESTING PLAN

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)	4K/day Hologic Panther; 2K/day Thermofisher	4K/day Hologic Panther; 2K/day Thermofisher	4K/day Hologic Panther; 2K/day Thermofisher	4K/day Hologic Panther; 2K/day Thermofisher	4K/day Hologic Panther; 2K/day Thermofisher	4K/day Hologic Panther; 2K/day Thermofisher	4K/day Hologic Panther; 2K/day Thermofisher	4K/day Hologic Panther; 2K/day Thermofisher	
FOR SEROLOGIC TESTING									
Number of additional* equipment and devices to meet planned testing levels	2	1	0	0	0	0	0	0	3

ELC ENHANCING DETECTION: TENNESSEE TESTING PLAN

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)	2K/day Abbott Architect	2K/day Abbott Architect	2K/day Abbott Architect	2K/day Abbott Architect	2K/day Abbott Architect	2K/day Abbott Architect	2K/day Abbott Architect	2K/day Abbott Architect	

* 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.