ELC ENHANCING DETECTION: CONNECTICUT TESTING PLAN

2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	Connecticut
Population Size:	3,565,000

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

The State of Connecticut has developed an adaptive, phased strategy to scale and implement testing to safeguard our community and fight COVID-19 in 4 phases. Each phase will coincide with our plans for progressive reopening of the state. Each phase has distinct goals and critical populations we aim to address as we ramp-up capacity. We will complement this widespread and ongoing COVID-19 RT-PCR testing with point prevalence testing in nursing homes, assisted living and other congregate settings.

As of May 29, 2020, at 8:30 PM, the total number of laboratory-confirmed and probable cases of COVID-19 reported among Connecticut resident is 42,022. Five hundred thirty-three patients are currently hospitalized with laboratory-confirmed COVID-19. There have been 3,912 COVID-19-associated deaths.

In May 2020, 104,232 Connecticut residents have been tested for SARS-CoV-2 by RT-PCR, many more than minimum threshold of 2% of our population or 7,100 residents. By the end of the year, we anticipate that our state-wide testing of the residents of Connecticut could exceed nearly 1.4M individuals per month depending on the course of the pandemic. Federal support will ensure we are able to reach our most vulnerable populations, scale testing to and beyond our current goal of 140,000 tests per week by June 20th, and implement appropriate public health interventions to protect Connecticut's 3.6M residents and support progressive reopening of our state.

The State of Connecticut testing strategy is built based on the following guiding principles. These inform our goals by phase and corresponding focus populations for prioritized testing: 1) monitor transmission and safeguard the health of the community, 2) protect and vulnerable residents, and 3) inform better decision-making on ongoing reopen strategies and protocols

Our approach to roll out this testing plan is dynamic by design. We will conduct critical information gathering in Phase 1 while safeguarding our residents, to inform our design and focus for later phases (e.g., using widespread surveillance in high-risk communities to detect community disease burden and re-allocate resourcing). We will remain vigilant during each phase of execution, and be prepared to take measured actions based on defined thresholds, e.g., shift our geographic focus to hot spots in vulnerable areas, increase testing frequency for healthcare/direct care workers who work in nursing homes, correctional facilities, etc. To do this, we will coordinate efforts across teams implementing testing with real-time data gathered at a central decision-making body.

PHASE 0 (MAY 1 – MAY 20, 2020)

- Target capacity: ~42,000 tests / week
- Goals: Test all symptomatic individuals
- Focus populations: All symptomatic individuals

PHASE 1 (MAY 21 – JUNE 20, 2020)

- Target capacity: Build to ~140,000 tests / week by June 20

- Goals: Goal from Phase 0, plus 1) Monitor transmission and safeguard the health of the community 2) Protect critical and vulnerable residents 3) Inform better decision-making on ongoing reopen strategies and protocols

- Focus populations (symptomatic & asymptomatic individuals): Populations from Phase 0, plus 1) Nursing home and Assisted Living Facility workers and residents 2) Corrections facility staff and incarcerated individuals 3) Members of high-risk communities through Federally-Qualified Health Centers, homeless shelters/lodgings 4) Health care workers 5) First responders

Phase 2 (June 21 – August 31, 2020)

- Target capacity: Build to 243,847 tests / week by August 31

- Goals: Goals from Phase 1, plus 1) Expand efforts to protect healthcare and other essential workers 2) Expand efforts to protect vulnerable populations

- Focus populations (symptomatic & asymptomatic individuals): Populations from Phase 1, plus 1) Expanded testing for nursing home & assisted living workers 2) Expanded testing for members of high-risk communities through Federally Qualified Health Centers, homeless shelters/lodgings

PHASE 3 (SEPTEMBER 1, 2020 – ONWARD)

- Target capacity: 243,877 tests / week plus additional capacity for public educational institutions

- Goals: Goals from Phase 2, plus provide broad testing to enable full reopening and reduce the probability of future outbreaks

- Focus populations (symptomatic & asymptomatic individuals): Populations from Phase 2, plus 1) Expanded testing for health care workers, 2) Expanded testing for nursing home residents, 3) Expanded testing for incarcerated individuals, 4) Faculty, staff, students of state universities and schools, and 5) Expand community base testing by neighborhood (focus informed by Phase 1-2)

a. TESTING PLATFORMS AND VENUES

As part of Unified Command, Connecticut has created a Testing Implementation Subgroup. This subgroup has created an online dashboard that includes daily updates on available testing capacity by laboratory as well as laboratory supplies and reagents. Testing across the state is orchestrated through a variety of venues to both ensure scalability and coverage in testing availability. Principally, Connecticut is partnering with six commercial and academic laboratories across the state to secure high-throughput capacity to test all required individuals by phase. All labs use high-throughput technology and will be able to process samples retrieved through NPS, OPS, or saliva-based methods (pending validation). The Connecticut State Public Health Laboratory (SPHL) also coordinates 2 mobile testing units that leverage the Abbott ID NOW Rapid technology to provide point-of-care testing to under-served regions throughout the state. Beyond this guaranteed capacity in state-coordinated venues, we continue to partner with our health systems and academic partners to ensure maximal testing coverage through their own in-house testing.

In Phase 0-1, we are leveraging existing equipment and technology, with a mix of swab/saliva methodologies for sampling. During this period, we will be primarily scaling our existing infrastructure (including for e.g.: , Hologic, and Thermo Fisher high-throughput systems). In Phase 2+, we are considering several options to increase testing capacity:

- Scale exactly as we do now: This is our default path. We will continue to scale with validated equipment and tests, then fold in new technologies and approaches to our strategy as they emerge.
- Alternate methods to scale using the same platforms: For example, using pooled testing and other methods to optimize the number of tests per batch, simplify operations, and reduce cost, once broader testing is required.
- Leverage new and innovative technologies: The state is evaluating several point-of-care platforms to rapidly scale capacity in Phase 2+

b. TESTING AT NON-TRADITIONAL LABORATORY SITES

To ensure testing coverage across the state, we are coordinating and promoting testing at a diversity of sites outside of the traditional healthcare and laboratory settings, including: pharmacies, federally-qualified health centers (FQHCs), first responder outposts (i.e., fire stations), corrections facilities, nursing homes and assisted living facilities, alternative residential facilities for homeless individuals, and varied sites through mobile testing Units (vans). The state's level of coordination and involvement at each of these sites depends on the existing footprint and capabilities. For example, at FQHCs, the state provides the sampling supplies (e.g., swabs and transport media), and samples are obtained by FQHC staff. In select nursing homes or other residential facilities, the Connecticut Department of Public Health (DPH) and National Guard coordinate not only supplies but also safe sampling and training of facility staff to ensure a sustainable model can be implemented. In this way, the state ensures essential protocols and supplies are in place to enable the site long-term.

c. USE OF SEROLOGICAL TESTING

At the present time, serological testing is widely available in Connecticut through either hospital or commercial laboratories. Based on electronic laboratory reporting, there have been 28,807 people who have had SARS-CoV-2 serological testing done in Connecticut. Of these, 23,115 people were tested in May.

The Connecticut SPHL is procuring multiple serological testing platforms to implement seroprevalence testing. The SPHL is looking into the feasibility of introducing a neutralization assay in the next few months.

In June 2020, a seroprevalence survey for SARS-CoV-2 among adults aged 18 and older in Connecticut including specific seroprevalence among high risk subgroups, with the opportunity for continued waves of testing. This activity will provide critical information to inform public policy, support mitigation strategies, and support CTs ongoing response, particularly regarding vulnerable populations. This public health practice activity is being conducted by the Yale School of Medicine and funded through the ELC Cooperative Agreement.

d. COMMUNICATION AND COLLABORATION AMONG THE BROAD TESTING COMMUNITY

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As part of Unified Command and for every focus population listed above, we have established a dedicated testing workstream with single accountable leads from the State to coordinate with contractors, local providers, and non-government coordinators who will be facilitating testing. Communications to the public regarding availability and guidance for testing will be developed from the Governor's office in coordination with these stakeholders. We have further established a robust process and central data repository to collect information daily from the network of sample collection sites and test processing laboratories to ensure that the statewide effort is coordinated and that bottlenecks are resolved. Our partners complete a required daily survey using a CT DPH portal, and all information is securely managed at the CT Emergency Operations Center by a dedicated team. In this way, we can support our partners with supplies or guidance as needed to ensure testing is not interrupted.

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*	104,232	408,018							512,250
Serology	23,115	30,000							53,115
TOTAL	127,347	438,018	0	0	0	0	0	0	

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**	**Platforms or devices used** (list all)	**Specific at-risk populations targeted** (list all)
40 FQHCs state-wide	Federally Qualified Health Center	State-contracted commercial labs	4,300			Racial and ethnic minorities, persons experiencing homelessness
~215 nursing homes	Other	State-contracted commercial labs	4,000			The elderly; nursing homes

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**	**Platforms or devices used** (list all)	**Specific at-risk populations targeted** (list all)
21 Corrections facilities	Other	State-contracted commercial labs	1,300			Prisons; incarcerated individuals
Hospital systems	Hospitals or clinical facility	Hospital / clinical labs, commercial labs	7,600			Racial and ethnic minorities, healthcare workers, persons experiencing homelessness
First responder sites	Community-based	State-contracted commercial labs	1,860			First responders
20 retail pharmacy sites	Drug store or pharmacy	Commercial labs	2,000			First responders, healthcare workers
111 Assisted Living Facilities	Other	Sate-contracted comercial labs	4,000			The elderly, other congregate living centers

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**	**Platforms or devices used** (list all)	**Specific at-risk populations targeted** (list all)
Statewide seroprevalence survey conducted by Yale School of Medicine	Commercial or private lab					Will include representative sampling of racial and ethnic minorities and by age

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. EXPANSION OF TESTING CAPACITY

The State of Connecticut strategy for expanding testing capacity is based enhancing the testing already being done at the Connecticut State Public Laboratory (SPHL) and enabling our local commercial partners to leverage existing infrastructure to scale and provide multiple redundant options for test execution.

1) CONNECTICUT SPHL:

Since the start of the COVID-19 pandemic, the Connecticut SPHL has consolidated all its personnel with molecular experience to respond a surge capacity resource to the SARS-CoV-2 molecular testing. Until mid-April, the SPHL provided COVID-19 PCR testing for all 30 of the acute care hospitals in Connecticut. Testing is being done 7 days a week with a turn-around-time between 24 and 48 hours. The SPHL plans to hire two (2) microbiologists and one (1) Public Health Laboratory Research Specialist using ELC funding. The Public Health Laboratory Research Specialist will initially be solely responsible for performing diagnostic test platform validation and/or verification of all ongoing COVID-19 assays. Additionally, the incumbent will be responsible for new assay development, new technology evaluation. The molecular microbiologist will be responsible for performing all COVID-19 testing procedures including extraction both manual and automated and PCR on 7500 ABI instruments. The second microbiologist will be responsible for tracking COVID-19 seroprevalence surveys testing procedures as a key priority in determining how widespread COVID-19 infection has been in a community. These positions are crucial to the SPHL's ability to sustain current workforce capacity and to provide critical support for the public health response to the COVID-19 pandemic.

2) STATE COORDINATED PARTNERS:

SAMPLING: The State of Connecticut has engaged partners across the state to establish sampling sites with a broad geographic footprint to ensure access for all CT residents. For example, by the end of June testing will be available at more than 12 pharmacy locations, 20 FQHCs, 215 nursing homes, 20 correctional facilities, many local fire houses or other first responder outposts, and conventional testing locations across our health systems.

LAB TEST EXECUTION: The State of Connecticut has entered into contracts with six local commercial and academic laboratories throughout the state that will ensure capacity is available to process hundreds of thousands of samples per week with a turn-around time that enables the CT DPH to take rapid action and put in place public health interventions to mitigate outbreaks and further spread of COVID-19. The following four laboratories became part of this network in May and another two laboratories will join the network in June: The Jackson Laboratory, Yale Laboratories, Genesys Diagnostics, and Sema4.

3) OTHER STATEWIDE TESTING CAPACITY:

Although not formally contracted by the state, our other partner organizations, such as hospital, academic, and regional commercial labs will serve as additional important sources of RT-PCR testing capacity. We will continue to encourage partners conducting local community outreach, such as community testing in churches, shelters, and other community sites to reach as many residents as possible.

B. PRIORITIZATION OF TESTING FOR VULNERABLE AND AT-RISK POPULATIONS

A core priority of the state-wide testing strategy is to provide widespread access to testing for persons and populations at high risk for serious illness and death from COVI-19. Beyond testing symptomatic individuals, our highest priority is to monitor transmission and prevent outbreaks through our statewide mass testing among asymptomatic individuals from the following focus populations: Nursing home and assisted living facility workers and residents, Corrections facility staff and incarcerated individuals, and members of high-risk communities.

As our testing capacity expands, we will ensure wider coverage and more frequent testing for individuals in these settings, including regular monitoring (~1x weekly) of health care workers and other staff in nursing homes, assisted living facilities, and correctional facilities and broader surveillance in some of Connecticut's hardest-hit and most vulnerable urban centers. Testing will be accomplished through a combination of state-facilitated initiatives in congregate settings, especially those that are licensed or operated by the state, together with widespread testing in high-risk communities and other congregate settings through FQHCs and community organizations.

In this way, we will maintain broad testing coverage to inform quarantine and isolation interventions to limit spread among our most vulnerable, all while supporting these individuals with wrap-around community supports (active monitoring, housing, food, well-being supports), that will enable safe isolation.

C. OVERCOMING BARRIERS TO EFFICIENT TESTING

We have developed a comprehensive issue identification and resolution framework and accompanying process to ensure roadblocks are removed such that both capacity and uptake of testing meet planned expectations. Namely, we have identified core constraints across every step of the testing journey, from the identification of a testing recipient through to case contact tracing, quarantine and isolation and wrap-around support. In this way, we address limiting steps in the process with the end goal in mind: ensuring testing access and enabling rapid intervention when positive cases are identified. A single-point-accountable lead from the state has been identified for each step of the testing journey and is responsible for identifying and resolving issues to drive to this common goal.

We have also instituted a process for integrating information along the testing journey to assess the impact of potential roadblocks. Daily mandatory surveys are completed by our sample collection site and lab partners to provide information about potential supply and capacity constraints, but also identify where capacity may be better utilized. These data are integrated with a central dashboard that allows the DPH and the State to assess several overarching metrics (such as time from symptom onset to result and contact tracing) to better understand effectiveness of our interventions.

D. DESCRIBE THE STRATEGY FOR SEROLOGY TESTING THROUGH THE PUBLIC HEALTH LABS, IF APPLICABLE, INCLUDING SPECIFIC PLATFORMS INTENDED TO BE USED.

The SPHL will purchase the Evolis (Bio-Rad) serology platform to implement seroprevalence testing. The SPHL is also looking into the feasibility of introducing a neutralization assay in the coming few months.

E. RESOURCE UTILIZATION AND SENTINEL SURVEILLANCE FOR VULNERABLE POPULATIONS

Connecticut will maintain broad testing surveillance among our most vulnerable populations, including regular, recurring testing of nursing homes, correctional institutions, and expanded sampling of asymptomatic and symptomatic individuals in high-risk communities and urban centers. By June 30, we intend for nearly half of all tests conducted each week in the state of Connecticut to be focused on these populations. To enable appropriate and timely intervention, testing will be complemented with constant Department of Public Health surveillance, automated contact tracing, and self-quarantine and isolation guidance, supported by over 700 public health professionals and trained volunteers. Throughout the notification and contact tracing process, we will embed health and wellness examinations, to guide residents to community supports (such as safe housing, food, and family supports) that will enable individuals to safely self-isolate. In this way, Connecticut will ensure adequate testing to detect future outbreaks, and complement this surveillance with rapid action to prevent widespread transmission among our most vulnerable residents.

F. DESCRIBE THE HEALTH DEPARTMENT'S PLAN TO EXPEDITE AND STREAMLINE PROCUREMENT, HIRING, AND ON-BOARDING OF NEW STAFF. SHOULD INCLUDE PLANNED STEPS AND ABILITY FOR THE JURISDICTION TO ACQUIRE SUPPLIES, REAGENTS, TEST KIT, COLLECTION MATERIALS REQUIRED FOR EXPANDING TESTING INDICATED IN TABLE #2 (BELOW)

All estimates contained in Table #2 were generated with reference to state contracted lab capacities. If the labs fail to meet their contracted targets by 20%, these estimates approximate what the state would need to procure to resolve those capability gaps. These estimates do not reflect the procurement needs of the state if the labs successfully meet their contracted capacities, nor do the estimates reflect the procurement needs if the labs fail to meet their demands by 100%. As a drafted template however, these estimates can be used to generate those figures.

PERSONNEL:

Personnel expansion is based upon a minimum requirement of 5 personnel certified to run real-time reverse transcriptase PCR procedures for the qualitative detection of SARS-CoV2 from assorted respiratory samples. The overarching CT testing strategy primarily depends upon high throughput laboratory workflows to meet increasing testing demand thresholds per month. As opposed to rapid point of care platforms such as the Abbott ID NOW or the Cepheid GeneXpert Xpress, which consolidate each procedural step of a PCR into one benchtop instrument, the average PCR workflow utilized in the biopharmaceutical laboratories contracted by the state possesses a structural organization that is multi-step and separated into distinct locations. At a minimum, there are three stations through which samples are moved in a unidirectional flow: reagent preparation, sample preparation, and amplification/analysis. Due to the numerous risks of cross-contamination posed in each one of these stations, it is necessary that they maintain both dedicated equipment and dedicated staffing. As testing demands increase each month, so does the volume of incoming samples into these labs, creating a workload bottleneck in receipt and processing tasks throughout. As a result, the 5 personnel accounts for the need for additional staffing in each of these 3 stations with placement of the final 2 personnel subject to structural variations that each of the contracted labs may possess.

The numbers that appear in row 8 were calculated using this baseline 5-personnel requirement multiplied by 6, which is the current quantity of the state's largest contracted labs (Yale, Genesys, Quest, Sema4, Jackson Labs, Hartford Health Care) to result in 30, with 60 reflecting each lab receiving two 5-personnel units.

EQUIPMENT:

Equipment expansion estimates are subject to a typical RT-PCR workflow, where the rate limiting equipment includes the nucleic acid extractor and the PCR analyzer, referencing common Thermo Fisher models utilized by our labs. These instruments are identified as rate-limiting because all other steps in the workflow involve rapid, repetitive tasks, the productivity of which can be increased at will by introducing more staffing into the laboratory. The operations of both the nucleic acid extractor and the PCR analyzer, however, cannot be influenced by the total staffing in the lab, and are instead subject strictly to the time required to perform their automated functions.

Figures that appear in row 9 were calculated to address the need for this equipment exclusively, where for every additional extractor that is procured so is another analyzer. This was decided for two reasons: 1.) the extractor and the analyzer were identified as the rate-limiting instruments; 2.) the extractor and the analyzer are high-value. Laboratory inventories will typically include over 50 line-items, and though most of these items are consumable, there are still a handful of large pieces of equipment that are needed to perform the procedure. Unlike the extractor and the analyzer, these pieces of equipment are not rate-limiting because they receive limited volume in the workflow and are subject to limited automation. This is also why we propose that the extractor and analyzer be procured together; if only one were procured, then the workflow would remain unaffected as samples would stack at the opposite machine. By procuring 1 of each at any given time, that lab has effectively doubled its capacity limit.

REAGENTS:

Reagent estimates are based on the Thermo Fisher TaqPath Combo kit, which includes enough primers, probes, and controls to run 1000 reactions. The Thermo Fisher MVPII nucleic acid extraction kit is also included in these estimates, and since these kits are each sufficient to run 2000 reactions, the ratio of needed reagents is 1: 2

SEROLOGY EQUIPMENT:

Serology equipment estimates reference the ELISA plate reader and the ELISA plate washer as the rate-limiting equipment for the serology diagnostic workflow, using the BioTek model. Like the extractor and analyzer of the PCR workflow, these instruments are automated devices that rely on a strict allotment of time to perform its functions rather than personnel to amplify its usage.

SEROLOGY REAGENTS:

Serology reagent estimates take into account the four reagents needed to perform a standard ELISA immunoassay. For the ELISA TMB, the referenced product is the 1-Step™ Ultra TMB-ELISA Substrate Solution (250 mL). For the ELISA Stop solution, this estimate uses a hydrochloric acid solution (1000 mL). For the spike antigen and HRP (Horseradish Peroxidase) reagents, this estimate uses a vial of 1 mL each, which are the standard packaged quantities for purchasing.

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	0	30							30
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	6							6
Volume of additional swabs needed to meet planned testing levels++	50,000	379,500							429,500
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels++	50,000	379,500							429,500

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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	380 - Thermofisher (tpCombo) 190 - TF MVPII							380 - Thermofisher (tpCombo) 190 - TF MVPII
FOR SEROLOGIC TESTING									
Number of additional* equipment and devices to meet planned testing levels	0	2							2
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	1 x ELISA Stop 3 x ELISA TMB 118 x HRP 118 x Spike Antigen							1 x ELISA Stop 3 x ELISA TMB 118 x HRP 118 x Spike Antigen

* 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.