

ELC ENHANCING DETECTION: DELAWARE TESTING PLAN

2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	Delaware
Population Size:	1,000,000

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

Delaware’s statewide program – which will allow for 80,000 tests in Delaware monthly – will be implemented in partnership with the Division of Public Health (DPH), the Delaware Emergency Management Agency (DEMA), Delaware hospital systems, primary care physicians, Federally Qualified Health Centers (FQHCs), urgent care centers, commercial pharmacies, and community organizations. Delaware’s new testing program is based on guidance from the U.S. Centers for Disease Control and Prevention.

The State of Delaware will prioritize testing under the new statewide program for:

- Any symptomatic individual.
- Anyone with known exposure to COVID-19.
- Vulnerable Delaware populations, including elderly Delawareans and members of low-income communities.
- Certain front-line essential workers.

DPH is currently conducting approximately 500 tests weekly at Delaware’s Public Health Laboratory in Smyrna, Delaware. Hospital systems are conducting more than 3,500 tests weekly through community testing sites statewide, and particularly in vulnerable communities where Delawareans have experienced higher levels of infection and transmission. Primary Care Physicians, Federally Qualified Health Centers, Urgent Care and Pharmacies will have an important role to play for COVID-19 testing and surveillance using a combination of PCR and antibody testing. Alongside these partners, Delaware will create a COVID-19 surveillance network to test symptomatic and asymptomatic individuals, with additional testing for vulnerable populations. The testing results from hospitals, primary care offices, Federally Qualified Health Centers, and Long-Term Care Centers are critical to track the activity of this virus and communicate risks to Delaware communities. Sample collection methods for testing vary based on the location the samples are being processed. Delaware is planning events to test the community in order to estimate volumes of specimen collection, which also determines the collection method. In partnership with Delaware’s health care systems, Delaware has established community testing sites in "hot spot" areas of Sussex County and in other vulnerable communities. Specimen collection kits, both in UTM and VTM as well as saline versions, with a mix of nasopharyngeal, nasal, and oral swabs, have been purchased and assembled from scratch by the State. Swabs and other collection kit supplies are now being provided by the Federal Government. The samples collected via this method can go to any testing site in the State, including the Delaware Public Health Laboratory which has multiple low volume and high-throughput extraction methods, such as a Thermo Fisher Kingfisher which

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can extract 500 samples/day, with extracted samples being run on the DPHL's seven Life Technologies ABI 7500 FAST DX instruments. In addition, the Delaware Public Health Laboratory has two Hologic Panther instruments which, if needed, can run 1,000 specimens per day each, with plans to upgrade these instruments to be able to run 2,000 per day each. Delaware also has expanded our serology testing by bringing on the SARS-CoV-2 testing method on the DPH Laboratory Abbott Architect instrument. The State of Delaware has purchased 200,000 saliva-based tests from Curative, a Los Angeles-based testing company that has supplied COVID-19 tests to Los Angeles and Atlanta. The purchase of 200,000 tests from Curative will dramatically expand the State's capacity to conduct PCR testing in primary care offices, community health centers, pharmacies, and in a variety of community settings to meet the needs of Delawareans where they are. These saliva tests, in addition to anterior nares swab tests sent to Delaware's Public Health Laboratory, and hospital-based testing, will constitute the State's primary testing mechanisms for at least the next several months. The Delaware Public Health Warehouse and Laboratory Warehouse are maintaining inventory and distribution records of test kits, supplies, and reagents. Staffing levels are being monitored by each individual agency within the State to ensure collection, distribution, and testing capacities at all capable facilities in the State. DPH is working to develop a list of priority employees to be tested and will continue to provide testing supplies, technical assistance, and educational materials to employers conducting additional testing. As Delaware begins to safely reopen our economy, we expect additional Delaware employers to express interest in employee testing programs. Essential employers who have testing capabilities may manage their own testing programs. Delaware continues to expand its testing capacity as the months of our plan unfold and partners expand their testing capacity. Given the dynamic situation with testing based on positive cases, vulnerable populations, and potential outbreaks, two testing collaboratives have been established to provide updates regarding approach and progress toward our goals. These regular meetings will allow for communication, collaboration, and coordination with the broad testing community at the local level (New Castle County, Kent/Sussex Counties) to ensure alignment. The monitoring of test kits, supplies, and reagent inventory occur at the state level through our Public Health Lab on a daily basis, and testing partners are asked to submit requests for resources through the State Health Operations Center (SHOC) to ensure appropriate allocation of resources.

Abbott ID NOW devices have been distributed to partners based on risk assessment, need for immediate results, and volume. The Department of Corrections (DOC), the Veteran's Home, FQHC's, and hospitals received these devices with the understanding of the limitation of the test; however, in these circumstances, the operational needs, the risk profile, or the baseline prevalence justifies the use of this methodology with option to confirm results at a laboratory. Delaware has recently partnered with the largest commercial pharmacy chain to provide COVID-19 testing at selected pharmacy retail stores. To enhance the efficiency of specimen processing, Delaware is purchasing LabWare mobile technology to allow for electronic data entry of specimens into LIMS and for electronic result reporting directly to clients. Also, emergency regulation has mandated routine testing of long-term care staff and consenting residents.

Regional multi-disciplinary testing collaboratives consisting of key stakeholders have been created to provide guidance on the overarching testing strategy. Regular outreach to testing partners includes

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regularly scheduled calls, press releases, the State of Delaware's COVID-19 website, Delaware's "My Healthy Community" website, and the distribution of the testing strategy to stakeholders to ensure alignment in approach and progress.

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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*	15,000	20,000	30,000	40,000	50,000	60,000	70,000	80,000	365,000
Serology	0	500	2,500	5,000	10,000	10,000	10,000	10,000	48,000
TOTAL	15,000	20,500	32,500	45,000	60,000	70,000	80,000	90,000	

*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)
DHSS Division of Public Health	Public health lab		2,500	300	general community, Latino community, African American community, homeless population, high-prevalence locations, senior high rises
AI DuPont	Hospitals or clinical facility		30	0	hospitalized patients
VA Hospital	Hospitals or clinical facility		20	0	hospitalized patients
St. Francis	Hospitals or clinical facility		30	0	hospitalized patients

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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)
Christiana Care	Hospitals or clinical facility		200	20	hospitalized patients
Bayhealth	Hospitals or clinical facility		30	0	hospitalized patients
BeeBe Medical Center	Hospitals or clinical facility		30	0	hospitalized patients
Nanticoke Memorial Hospital	Hospitals or clinical facility		30	0	hospitalized patients
Long-Term Care Facilities	Hospitals or clinical facility	LabCorp/Quest, State Lab	1,000	100	Long-Term Care residents/staff
Delaware Emergency Management Agency	Community-based	KorvaLabs, Inc.	200	0	general community, Latino community, African American community, homeless population, high-prevalence locations, senior high rises
Medical Offices	Hospitals or clinical facility	LabCorp/Quest, State Lab	200	100	
Westside Family Healthcare	Federally Qualified Health Center		80	0	general community, Latino community, African American community, homeless population, migrant workers

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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)
Henrietta Johnson Medical Center	Federally Qualified Health Center		20	0	general community, Latino community, African American community, homeless population, migrant workers
La Red Health Cater	Federally Qualified Health Center		40	0	general community, Latino community, African American community, homeless population, migrant workers
Rite Aid	Drug store or pharmacy		20	0	
CVS	Drug store or pharmacy		20	0	
Walgreens	Drug store or pharmacy		20	0	
Hospital Public Testing Sites	Drive-thru testing site	LabCorp/Quest	300	0	
Hospital Community Testing Sites	Community-based	Curative-Korva, State Lab	250	0	general community, Latino community, African American community, homeless population, meat-processing plant workers

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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.

At the start of the COVID-19 outbreak, Delaware hospitals were the primary submitters of COVID-19 suspect patients to the Delaware Public Health Laboratory (DPHL) because DPHL was the only laboratory in Delaware to have the capability to perform and report SARS-CoV-2 diagnostic test results within 24 hours. The DPHL tested specimens using the CDC approved method for Real-Time Reverse Transcription-Polymerase Chain Reaction (rRT-PCR). To this end, manual extraction methods, various automated extractor platforms, and Applied Biosystem 7500 FAST DX instruments (DNA amplification and identification) were used following the completion of protocols to verify performance (verification). Hospitals eventually on-boarded their own testing methods. As a result, DPHL received a greater number of specimens from Long Term Care (LTC) facilities and correctional facilities. Going forward, DPHL plans to increase testing capabilities in order to prioritize testing industrial personnel, such as in the poultry industry, as the State of Delaware is one of the largest poultry producers in the United States. DPH is currently working with private business in the industries mentioned prior and for at-risk populations as a whole to efficiently sample and distribute samples to appropriate laboratories for testing, not just at the Public Health Laboratory but at other testing facilities within the Jurisdiction. Beyond this, DPHL intends to increase testing for populations that are homeless and underserved. In addition, DPHL has distributed 14 Abbott ID NOW instruments to various facilities including State Service Centers (SSCs) and correctional facilities to provide patients with more rapid point of care tests and testing results. DPHL has also purchased and deployed over 15,000 rapid antibody tests to allow for improved and increased drive-through testing and increased rapid testing of vulnerable populations. DPHL also intends to continue critical care testing, when needed, and to implement surveillance testing by recruiting submitters while emphasizing the importance of public health laboratory specimen submission to meet the goals of the "right size program" (population-based surveillance) and improving SARS-CoV-2 surveillance.

Lab results will be submitted into the state surveillance system (Delaware Electronic Reporting and Surveillance System - DERSS) electronically or manually given the different types of testing modalities. This data will be shared internally to assist with strategic planning and publicly on My Healthy Community website. DPH Epidemiologists will have access to the testing data to perform case investigations and contact tracing.

Planned expansions of existing capacity include procurement of new testing equipment or device platforms, particularly those that can perform high-throughput, and ability to augment staffing through cross-training and contracts to scale up testing capacity rapidly. We have strike teams composed of public health staff and health care partners that can set up temporary or mobile testing sites based on impacted populations and number of cases implying a potential outbreak. Examples of such operations include testing at poultry plants, "hot spot" communities, and high rises housing vulnerable populations. Testing needs of vulnerable and at-risk populations will be prioritized for these temporary or mobile

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testing sites given access barriers to traditional testing sites, based on general surveillance or number/acuity of positive cases, particularly those requiring hospitalization or those related to an outbreak investigation. In addition to testing services, DPH offers social services to address barriers to infection control practice in the home or community environment, particularly for those residing in underserved communities or minorities (e.g., care kits to support infection control practices at home, hotel accommodations for suspected or confirmed cases). For those populations that have access to testing resources, such as long-term care facilities, DPH supplies specimen collection kits and lab processing if requested, especially when routine testing for residents and staff is recommended. DPH has expanded the sentinel surveillance network to target vulnerable populations through partnerships with Federally Qualified Health Centers and ambulatory offices serving these populations. Specimen collection kits, lab processing, educational materials in different languages, and technical assistance are offered to sentinel providers. DPH is also partnering with community stakeholders to offer widespread testing regardless of symptoms, including health systems and commercial pharmacies. Overall, many different approaches have been developed and implemented to address the different barriers to traditional testing processes:

1. Utilize multiple laboratory types - State Public Health, Commercial, Private, Hospitals, Primary Care Network (e.g., community testing sites)
2. Utilize public health staff, MRC, EMS, and health care partners to collect/transport samples and assist with outbreaks (e.g., poultry plants, community testing sites, vulnerable populations)
3. Employ multiple testing strategies - Baseline, small sample surveillance testing, sentinel surveillance, outbreak response, repeat testing of all LTC staff and residents
4. Use rapid tests (Abbott ID NOW, rapid antibody tests) to test at-risk or under privileged communities
5. Develop contracts with health partners (e.g., health systems, staffing agencies) for surge capacity
6. Hire health educators for community outreach/engagement (e.g., community health workers)
7. Partner with community groups to assist with means to reach underserved populations (e.g., medical providers/offices, church leaders, community leaders)

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Delaware is proceeding with testing but is working on overcoming barriers in the way of a typical testing process, including logistics, supply-chain, and capacity. Logistic capacity is dependent on a few areas of strength: courier services and data logistics. With multiple large-scale collection events taking place throughout the State, additional couriers are required to aide existing DPHL couriers who must maintain their daily routes in order to collect SARS-CoV-2 specimens from main sites such as hospitals. Three contractual couriers will be hired to aide in receiving and delivering the abundant level of samples throughout the state in order to sustain a two-shift operation over a seven-day period. The contract couriers would run routes on our second shift 7 days a week. Data logistics comes in the form of an improvement needed to the specimen and test result data entry and reporting automation process. DPHL is hiring temporary data-entry technicians while working with our LIMS vendor to automate the data entry process in order to handle high-volumes of test results. Supply-chain issues exist but are only being alleviated in any capacity due to assistance of CDC distribution programs of collection supplies and reagents through the IRR Program. DPHL is expanding the laboratory reagent storage capacity to better handle longer periods of reagent storage, as our reagent supply was greatly impacted. In order to accommodate for high demand for testing, the acquisition of more extractors is essential. Experience from the SARS-CoV-2 pandemic has made it a reality that it is imperative to expand laboratory-testing capacity to levels above and beyond what was previously considered. When testing capacity is expanded, so must also be the number of staff. For this reason, contractual microbiologists to aid in processing of samples and for surveillance testing are being hired to expand capacity.

DPHL will continue to implement CDC approved methods for rRT-PCR testing with the purchase of additional extractors including a Qiagen QIAcube and Roche MagNA Pure 24 to increase throughput for these methods. DPHL currently has two Hologic Panther Systems and anticipates the purchase up to four additional instruments for high-volume automated testing. DPHL also intends to incorporate SARS-CoV-2 surveillance with the Influenza-Like Illness (ILI) surveillance program. To do this, the plan is to purchase the Panther Fusion expansion, which uses an FDA approved RT-PCR method for SARS-CoV-2 testing as well as testing capabilities for influenza. Beyond the mentioned improvements, DPHL also intends to further improve public health surveillance for SARS-CoV-2 by using next generation sequencing (NGS). With current funding, DPHL will purchase a NextSeq system and reagents (library preparation, primers, beads, cartridges) for NGS for SARS-CoV-2. Another test method used at DPHL is serological testing. It identifies antibody production in response to infections. This approach can help to establish people which have been exposed to SARS-CoV-2 and results used to determine guidelines for return to work policies. Within this type of immunoassay testing method is the Abbott ARCHITECT i1000sr. DPHL recently added the SARS-CoV-2 IgG Assay to the instrument. The ARCHITECT is being used to test serum and plasma specimens for SARS-CoV-2 IgG. This gives DPHL the potential of testing 4,000 patients per week. Due to the increased instrumentation in order to increase testing capabilities and throughput, a laboratory addition has already been pursued with an architect providing an estimate to increase the square footage of the laboratory. This increased space will allow for DPHL to properly house and utilize the new and current instrumentation to increase testing of critical care patients and to shift to “right size” surveillance of SARS-CoV-2.

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Delaware Public Health's plan for resource utilization and managing testing is robust. Our partnerships with sentinel providers, while strong, have opportunities to expand. While the DPH Laboratory will continue to perform SARS-CoV-2 surveillance testing, we anticipate supporting key partners within the jurisdiction, such as hospitals, to ensure they are able to perform testing and care for vulnerable populations without dependence on the State Laboratory. The goal is to strengthen partners' capacity alongside Delaware Public Health's capacity by assisting with staffing, instrumentation, and other resources as needed. This support will continue throughout the lifetime of federal grant support and will be assessed throughout that period. By utilizing the capital provided to Delaware, community mitigation is also being tackled on all fronts from raising awareness via media and contact tracing and epidemiological connections directly to positive individuals.

During SARS-CoV-2 response, the State of Delaware has raised the bar in expediting and streamlining processes that normally took far longer. Delaware anticipates these procedures regarding streamline to continue through December, 2020.

Streamlining Procurement:

Delaware DHSS was given purchase exceptions, allowing DPHL to purchase instrumentation and bypassing certain State-mandated headwinds regarding contract thresholds. DEMA has been working with DPH and the rest of the State in order to procure necessary supplies for testing, specimen collection, PPE, and more. Procurement has been further streamlined by giving DPH permission to purchase high volumes of supplies and reagents off of RFP-driven mandatory-use State contracts, allowing DPHL to purchase supplies from vendors that never would have been possible to do business with before.

1. Delaware OMB removes certain restrictions on purchasing
2. New set of vendors are accessible
3. Wider variety of collection supplies and testing reagents, as well as PPE, available within faster timeframes from multiple supply chains
4. CDC provides shipments of collection kits and supplies
5. IRR provides reagents for approved instruments to test SARS-CoV-2
6. DPHL supplements distributions with purchases using awarded grant funds.
7. Scale up purchasing of supplies for increased testing volumes
8. Distribute supplies and resources to partners within the jurisdiction as necessary.

Streamlining Hiring and On-Boarding:

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DPH has been granted permission to post brand new positions for contact tracers and epidemiologists and has initiated new ways of data entry training via remote training sessions hosted by the DPHL LIMS Administrator.

1. DPH identifies needs of staffing
2. State authorizes public posting of positions in need for SARS-CoV-2 response
3. CDC Foundation assists with staffing needs in Delaware
4. Grant funds allow the hiring of positions in response to SARS-CoV-2 such as contact tracers, supervisors, budget staff, laboratory staff, and epidemiologists.
5. Group and remote trainings to be held to onboard dozens of staff at a time for quickest and most efficient response times.
6. Distribute trained staff resources to partners within the jurisdiction as necessary.

Below is the instrumentation plan for the Delaware Public Health Laboratory:

Diagnostic:

May: Currently using for COVID Abbott ID NOW (distributed) (15), Qiacube(2), MagNa Pure 96 (1), MagNa Pure Compact (2), King Fisher (1), ABI 7500 (7), Panther Systems (2).

June: Additionally purchasing for SARS-CoV-2 response: Qiagen EZ1 (2), Panther Plus (2), Panther Fusion (2), epMotion liquid handling (1), NextSeq (1), MagNa Pure 24 (1), QIAcube (1).

July-December: In anticipation of a completed Laboratory expansion, to be purchased for COVID are Panther Systems (2), Panther Plus (2), Panther Fusion (2).

Serological:

May-December: Currently using for COVID is the Abbott Architect (1), and non-instrument serological lateral flow immunoassay rapid test. DPH does not anticipate expanding serological testing capacity through December with our diagnostic strength and partner strength.

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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	35	2	9	0	0	0	0	0	46
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)	30	10	0	0	0	0	0	6	46

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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	10,000	20,000	30,000	40,000	50,000	50,000	200,000
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels ⁺⁺	0	0	10,000	20,000	30,000	40,000	50,000	50,000	200,000

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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)	Reagents for tests per month: Qiagen-1k; Roche-1k; Hologic-56k; Thermo(kingfisher)-35k	Reagents for tests per month: Qiagen-1k; Roche-1k; Hologic-56k; Thermo(kingfisher)-35k	Reagents for tests per month: Qiagen-1k; Roche-1k; Hologic-56k; Thermo(kingfisher)-35k	Reagents for tests per month: Qiagen-1k; Roche-1k; Hologic-56k; Thermo(kingfisher)-35k	Reagents for tests per month: Qiagen-1k; Roche-1k; Hologic-56k; Thermo(kingfisher)-35k	Reagents for tests per month: Qiagen-1k; Roche-1k; Hologic-56k; Thermo(kingfisher)-35k	Reagents for tests per month: Qiagen-1k; Roche-1k; Hologic-56k; Thermo(kingfisher)-35k	Reagents for tests per month: Qiagen-1k; Roche-1k; Hologic-56k; Thermo(kingfisher)-35k	
FOR SEROLOGIC TESTING									
Number of additional* equipment and devices to meet planned testing levels	1	0	0	0	0	0	0	0	1

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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)	Reagents for tests per month: Abbott 50k, Healgen Rapid 15k	Reagents for tests per month: Healgen Rapid 15k	Reagents for tests per month: Healgen Rapid 15k	Reagents for tests per month: Healgen Rapid 15k	Reagents for tests per month: Abbott 50k, Healgen Rapid 15k	Reagents for tests per month: Healgen Rapid 15k	Reagents for tests per month: Healgen Rapid 15k	Reagents for tests per month: Healgen Rapid 15k	

* 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.