

ELC ENHANCING DETECTION: NORTH DAKOTA TESTING PLAN

2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	North Dakota
Population Size:	762062

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

The North Dakota Department of Health (NDDoH) has already surpassed the goal of testing 2% of its population each month. In May, the NDDoH is supporting PCR testing of 2,500 people per day, which would be 75,000 people (10% of the population). The NDDoH plans to expand this testing to 8,000 tests (diagnostic and serology) per day or 248,000 tests per month (33% of the population) between diagnostic and serology.

The North Dakota public health laboratory has been approved to hire 139 additional staff to support the COVID-19 response. The National Guard is currently assisting the laboratory with putting together SARS-CoV-2 collection kits, shipping them to the ordering facilities, demographic entry, receiving of SARS-CoV-2 specimens in the laboratory, and facilitating the distribution of Abbott ID Now reagent kits throughout the state. In addition, they have also helped in the coordination of long-term care testing events and drive up testing events. The laboratory has already hired about eighty additional temporary employees for demographic entry, receiving of SARS-CoV-2 specimens in the laboratory, performing SARS-CoV-2 PCR and serology tests, and reporting results. Additional areas will need to be hired as the workload continues to increase.

The North Dakota public health laboratory can process specimens within 48 hours of receipt. The lab performs PCR on SARS-CoV-2 specimens utilizing the Abbott M2000, the ThermoFisher assay with the ABI 7500 Fast Dx, and the Cepheid GeneXpert. Training on the Hologic Panthers has just been completed as well. In addition, serology tests are performed on the Abbott Architect and the Diasorin Liaison. The abundance of test platform options enhances high throughput volumes for the state of North Dakota, specifically with the Abbott M2000, ABI 7500 Fast Dx and Hologic Panther instruments for PCR tests.

The NDDoH recently entered into a contract with Mako Medical to provide 4,000 additional SARS-CoV-2 PCR tests.

A number of health systems across the state have their own testing capabilities and account for about 500 tests per day. The NDDoH is aware of additional private laboratories that are bringing on the capability to conduct diagnostic and serological testing.

The North Dakota public health lab will continue to process specimens for diagnostic testing for private health care facilities. This currently accounts for about 400 specimens each day.

Forty Abbott ID Now machines are placed across the state at Indian Health Services, tribal health, hospitals, and critical access hospitals. Twenty-six reagent kits are sent out each week by the North Dakota public health lab that can perform tests on twenty-four specimens each week per kit. These machines allow for facilities to receive more timely results.

Vulnerable populations, including residents and staff of long-term care, group homes, correctional facilities, homeless shelters, etc. will continue to be prioritized for testing. Point prevalence testing has

ELC ENHANCING DETECTION: NORTH DAKOTA TESTING PLAN

occurred and will continue to occur across the state in congregate living facilities. It is planned to point prevalence testing in long term care facilities will occur every 7-10 days. If positives are identified in these settings, repeat testing will occur 7-10 after the initial testing until positives are no longer identified.

Mobile testing is and will continue to be deployed to communities and workplaces experiencing outbreaks. The National Guard, NDDoH, and local public health are currently being used to staff mobile testing. Testing teams are able to deploy rapidly (next day). Specimens are collected in a drive-thru and then couriered to the North Dakota public health lab for processing. In the future, the NDDoH would like to have two mobile units with high throughput equipment to process specimens on site. An online form is available for communities to request testing events.

The Governor of North Dakota issued an executive order in March allowing pharmacists to collect specimens for COVID-19 testing. This allows a non-traditional provider to collect specimens, expanding North Dakota's capacity.

The NDDoH plans to implement sentinel surveillance testing in private health care settings of asymptomatic pregnant women and preoperative patients. Facilities will be asked to routinely screen asymptomatic pregnant women and preoperative patients and submit specimens to the NDDoH. This information will be used to identify asymptomatic cases and gain a better understanding of the occurrence of COVID-19 in the community. Pregnant women will account for about 350 tests per week.

Serologic testing using the Abbott Architect and Diasorin Liaison are currently available at the NDDoH and will be used for seroprevalence testing in the future. About 100 serologies are ordered from the NDDoH daily. The NDDoH serology strategy is currently in development. The NDDoH intends to contract with two universities to conduct seroprevalence studies. The NDDoH will collaborate with these universities to determine priority groups for seroprevalence studies. Additionally, serology will be used in congregate settings or workplaces with at least five percent of the population being PCR positive.

The NDDoH has access to three different point-of-care serologies: Biosys RDT test (Biosys Laboratories S Pasadena, CA), Biocan RDT test (Biocan Diagnostics BC, Canada) and Covisure RDT test (Cardinal Laboratories WHPM Inc Irwindale, CA). A number of point-of-care serology tests are currently being validated and compared to the results of the Abbott Architect. This validation will occur in three phases. Phase I will encompass initial serology Rapid Diagnostic Testing (RDT) validation with known positives and utilize the Abbott Architect serology as a control due to the high Positive Predictive Value (PPV) and high Negative Predictive Value (NPV). Estimated time to completion is 2 weeks from validation proposal to completion. Phase II will encompass deployment of validated serology kits to local areas that meet criteria: businesses/local public health willing and capable to utilize tests, known areas where prevalence is greater than or equal to 5%. This phase will take two to six weeks to complete from deployment to follow up. Phase III is continuous close follow up with occupational health at facilities and businesses where kits were sent. Estimated time for this evaluation is unknown however, expect 6-12 month timeframe or until effective treatment and/or vaccine is developed.

Communication and coordination of a broad testing community poses amazing opportunities to innovate and advance our laboratory procedures. The keystone to the success of such an expansive endeavor is collaboration, thus, positioning precise, timely, and reliable communication at the top of the operational priorities. This necessary level of sophisticated coordination has been built from the ground

ELC ENHANCING DETECTION: NORTH DAKOTA TESTING PLAN

up with the sole purpose of being able to not only withstand the pressures of testing such immense volumes but thrive and adapt to the ever-changing environment we find ourselves in. Dematerialization is the focus of this evolution. We have embraced technology and the digitalization of our complete inventory system. By leveraging the collaborative capabilities in inventory management along with having an unprecedented level of communication deep within supply channels we are more prepared than ever to make data-based decisions on supply shortfalls or faulty batches of liquid consumables. Both of which are capable of crushing a scientific operation of this magnitude. Consistent communication between sections of these processes combined with accountability through these new additions to our technical assets has given us the ability to not only account for what is on our shelves or in route, but we now operate on a model of reconciliation and responsibility with our products and materials going in and going out of laboratory. North Dakota has a state public health lab that has used the pressures and adversities caused by this pandemic to transform itself into an efficient and accurate manufacturing and distribution 'business' by remaining disciplined in our approach of a resource-based view to guide us into the future.

ELC ENHANCING DETECTION: NORTH DAKOTA 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*	77,500	105,000	124,000	155,000	240,000	248,000	240,000	248,000	1,437,500
Serology	1,000	3,000	6,200	9,300	18,750	19,375	18,750	19,375	95,750
TOTAL	78,500	108,000	130,200	164,300	258,750	267,375	258,750	267,375	

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 throughput	Daily serologic throughput	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
private health care providers	Public health lab		600	100		Symptomatic patients seen at private clinics and hospitals. Asymptomatic close contacts to COVID positive cases.

ELC ENHANCING DETECTION: NORTH DAKOTA TESTING PLAN

Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic throughput	Daily serologic throughput	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
long term care and congregate living facilities	Public health lab		4,500	0		Point prevalence testing of long term cares, group homes, correctional facilities, homeless shelters and other congregate settings with vulnerable populations. Testing according to CMS guidance for reopening nursing homes. Testing is for both staff and residents.
testing response in congregate settings	Public health lab		1,000	200		Retesting of congregate living facilities with positives

ELC ENHANCING DETECTION: NORTH DAKOTA TESTING PLAN

Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic throughput	Daily serologic throughput	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
mobile testing	Public health lab		500	300		Community-wide testing in various locations
community outreach	Public health lab		300	25		Symptomatic patients seen at local public health units or critical access hospitals
sentinel surveillance	Public health lab		350	0		Routine testing of asymptomatic individuals at private clinics and hospitals. pregnant women at time of delivery, pre-operative testing and testing of health care workers.

ELC ENHANCING DETECTION: NORTH DAKOTA TESTING PLAN

Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic throughput	Daily serologic throughput	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
long term care and congregate living facilities	Commercial or private lab	Mako Medical	133	0		Point prevalence testing of long term care, group homes, correctional facilities, homeless shelters and other congregate settings with vulnerable populations. Testing according to CMS guidance for reopening nursing homes. Testing is for both staff and residents.
private health care providers	Commercial or private lab	University of North Dakota	300	0		Symptomatic patients seen at private clinics and hospitals. Asymptomatic close contacts to COVID positive cases.
Seroprevalence Studies	Other	TBD	0	300		TBD population and number of tests. Planning to contract with the University of North Dakota and North Dakota State University for two studies.

ELC ENHANCING DETECTION: NORTH DAKOTA 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.

North Dakota is very rural and there is increasing demand to improve turn-around time. To address this need, we will purchase two mobile laboratories along with 4 Cepheid GeneXperts to provide faster results while at the location of collection. Serology will also be included using 2 additional Diasorin Liaison instruments.

To help further increase capacity, the NDDoH has entered into an agreement with Mako Medical to provide 4,000 additional SARS-CoV-2 PCR tests during a trial period. Depending on the success of the trial period, the agreement may extend to additional SARS-CoV-2 PCR tests to help expand additional capacity.

At this time, the ND National Guard is supporting the building and distribution of specimen collection kits around the state. As their orders expire, we need to identify long-term plans. Therefore, additional employees are being hired and an agreement with a local community college is being established to help fill this role.

Vulnerable populations, including residents and staff of long-term care, group homes, correctional facilities, homeless shelters, etc. will continue to be prioritized for testing. Point prevalence testing has occurred and will continue to occur across the state in congregate living facilities. It is planned to point prevalence testing in long term care facilities will occur every 7-10 days. If positives are identified in these settings, repeat testing will occur 7-10 after the initial testing until positives are no longer identified.

The NDDoH public health laboratory has overcome obstacles regarding supply shortage by diversifying and adding additional PCR instruments so there is never a stop in testing. In addition, standing orders have been arranged and we are working closely with the vendors to ensure deliver of reagents and consumables testing continues. With the addition of the digitalized inventory system, supply status can be accounted for in real time.

The NDDoH has already increased staff to include microbiologists, laboratory support, administrative support, etc. To streamline the process, we have worked with Traveling Tech agencies, ND's Workforce Coordination Center and the Emergency Operations Center to expedite the process. We will continue to work with these agencies and others to hire the last remaining additional staff.

ELC ENHANCING DETECTION: NORTH DAKOTA 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	63	43	20	10	3	0	0	0	139
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)	5	3	3	4	2	0	0	0	17
Volume of additional swabs needed to meet planned testing levels ⁺⁺	78,120	168,255	190,890	190,890	216,000	190,890	216,000	190,890	1,441,935
Volume of additional media (VTM, MTM, saline, etc.) needed to meet	78,120	168,255	190,890	190,890	216,000	190,890	216,000	190,890	1,441,935

ELC ENHANCING DETECTION: NORTH DAKOTA TESTING PLAN

BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
planned testing levels**									
Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher)	2511/day- Thermofisher; 1410/day- Abbott M2000; 190/day- Cepheid GeneXpert	2511/day Thermofisher; 2250/day Hologic panther; 1410/day Abbott M2000; 190/day Cepheid GeneXpert	2511/day Thermofisher; 2250/day Hologic panther; 1410/day Abbott M2000; 190/day Cepheid GeneXpert	2511/day Thermofisher; 2250/day Hologic panther; 1410/day Abbott M2000; 190/day Cepheid GeneXpert, 800 Abbott Alinity M	2511/day Thermofisher; 2250/day Hologic panther; 1410/day Abbott M2000; 190/day Cepheid GeneXpert, 2400 Abbott Alinity M				
FOR SEROLOGIC TESTING									
Number of additional* equipment and devices to meet	1	0	0	0	2	0	0	0	3

ELC ENHANCING DETECTION: NORTH DAKOTA TESTING PLAN

BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
planned testing levels									
Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher)	1000/day- Abbott Architect; 1700/day- Diasorin Liaison	1000/day- Abbott Architect; 1700/day- Diasorin Liaison	1000/day- Abbott Architect; 1700/day- Diasorin Liaison; Rapid Serology Kits	1000/day- Abbott Architect; 1700/day- Diasorin Liaison; Rapid Serology Kits	1000/day- Abbott Architect; 1700/day- Diasorin Liaison; Rapid Serology Kits	1000/day- Abbott Architect; 2000/day- Diasorin Liaison; Rapid Serology Kits	1000/day- Abbott Architect; 2000/day- Diasorin Liaison; Rapid Serology Kits	1000/day- Abbott Architect; 2000/day- Diasorin Liaison; Rapid Serology Kits	1000/day- Abbott Architect; 2000/day- Diasorin Liaison; Rapid Serology Kits

* 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.