

ELC ENHANCING DETECTION: MARYLAND TESTING PLAN

2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	Maryland
Population Size:	6,000,000

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

a.) Expanded testing capacity is one of the four pillars of Governor Hogan’s Maryland Strong: Roadmap to Recovery. Maryland is pursuing a four-pronged approach for increasing its state-wide laboratory testing capacity towards the short-term goal of sustaining more than 10,000 reverse transcription polymerase chain reaction (RT-PCR)-based COVID-19 tests a day, and expanding to 20,000 tests a day:

1. Expanding internal state public health lab (SPHL) capacity;
2. Creating partnerships with commercial and academic labs to enhance use of their capacity;
3. Pursuing other strategic opportunities through work with manufacturers of point-of-care testing systems to clarify how to best deploy safe and accurate diagnostic systems, coordination with private hospital laboratories, and pursuing a White House offer to make use of Maryland-based federal laboratories; and
4. Laying the foundation for a statewide serological-test-based survey to estimate the prevalence of prior COVID-19 infection in the state.

Maryland’s SPHL has a daily capacity of 970 RT-PCR tests. Work is currently in progress to acquire, adapt and/or outfit the following analytical platforms to significantly increase current SPHL capacity. Recently, the Abbott M2000 RealTime System was successfully repurposed for SARS COV-2 testing. In addition, the SPHL is working to bring the following high-volume platforms online for additional capacity:

- Hologic Panther (Repurposed for SARS CoV-2 testing)
- MGISP-360 (Significantly expands RNA extraction throughput)
- ABI 7500 Fast dx Real PCR Instrument (RNA amplification)
- Biomerieux EMAG (RNA extraction)

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Further, a Lab Web Portal has been established to facilitate electronic ordering of and reporting of SARS-CoV-2 tests for clients of the SPHL.

In addition to lab equipment and supplies, it is essential for MDH to apply ELC Paycheck Protection Program and Health Care Enhancement Act (PPHCE) and CARES Act funds to expand the SPHL workforce by adding additional laboratory staff and the laboratory information management system (LIMS) and electronic test orders and results (ETOR) infrastructure needed to operate up to 3 shifts per day/7 days per week.

Abbott Rapid ID NOW

Maryland plans to distribute the Rapid ID NOW system at hospitals throughout Maryland. The SPHL currently possesses 15 Abbott Rapid ID NOW instruments and HHS is providing the SPHL with approximately 1200 cartridges/tests per week. The SPHL has recently completed a survey of interested hospitals to determine how to most effectively deploy this important resource. After a thorough review of the survey results, the SPHL team will deploy the Rapid ID NOW machines to moderate and high complexity CLIA certified hospital laboratories that have a demonstrated need to locally perform COVID-19 point-of-care testing in strategic locations throughout Maryland.

Innovative Academic and Commercial Partnerships

The MDH has had a long and productive partnership with the University of Maryland, Baltimore (UMB). UMB is a nationally recognized center for world-class biomedical research, education and practice. As such, UMB has been a premier partner with the State in mounting a comprehensive approach to coronavirus testing. In April 2020, Dr. Deborah Birx, of the White House Coronavirus Task Force, urged America's Governors to "unleash" the assets of the research laboratories in their states. Earlier that month, MDH entered into an agreement with the UMB School of Medicine to convert a powerful research laboratory at the Institute for Genome Sciences to a full-scale clinical lab to support the pandemic response needs of the State of Maryland. No better example exists in the country of an innovative academic and public health partnership to convert and launch vital diagnostic testing to support this urgent health crisis.

Fully maximizing the capabilities of the UMB laboratory, and relying on Maryland's highly skilled in-state expertise and assets, is a cornerstone of the State's entire testing strategy.

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Under this partnership, the UMB laboratory has acquired new high-throughput equipment and supplies, scaled up its workforce, and developed the necessary IT and logistics capabilities required to operate a full scale clinical lab. This remarkable conversion has been successfully accomplished in a matter of weeks. The UMB lab is on track and positioned to become the central supplier of the State's sustained high-volume RT-PCR diagnostic testing for years to come. The UMB lab has begun processing tests to support the major initiative of universal testing in all Maryland nursing homes and will continue to increase testing volumes, employing high quality, FDA approved equipment and supplies, including high quality PCR assays secured by the State from South Korea.

The combination of an extraordinary State acquisition of test assay kits, along with the remarkable asset represented by the UMB laboratory, and the multiple other supply and deployment initiatives noted in this Plan, form the foundation of Maryland's overall, long-term Testing Strategy.

For information about items b-d, please see the responses below. b.) To deploy the increased laboratory capacity, Maryland has many different venues where testing occurs, including community-based testing sites (ex. retail, pharmacies, and community centers), hospitals, skilled nursing facilities, detention centers, and urgent cares and other private locations. All known testing locations are available to the public at <https://coronavirus.maryland.gov/>.

The COVID-19 testing deployment strategy in Maryland has been to:

- 1) Stand up specimen collection locations that are accessible via drive through, including regional sites capable of handling large (1000-2000) volumes of vehicles per day. Beginning in April 2020, Maryland leveraged existing Vehicle Emissions Inspection Program (VEIP) infrastructure to provide drive-through testing in non-traditional locations for specimen collection, with nine sites currently operational and at least 4 regional sites capable of high-volume throughput;
- 2) Develop smaller community-based, mobile testing to reach high-risk populations or those with poor access to health care, in partnership with community and faith-based organizations as well as federally qualified health centers;
- 3) Conduct facility-based testing in nursing homes, assisted living facilities and group homes as well as state detention centers. These locations have a more vulnerable population and also have had multiple outbreaks. This has included efforts nearly completed to conduct universal testing at skilled nursing facilities for residents and staff, in coordination with the National Guard and the Defense Medical Forces with HHS. Because of the high positivity and mortality rate in these facilities, supporting services, such as staffing, and medical assessment are necessary to ensure the safety of residents and staff.

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Additionally, the Governor has ordered universal testing in Maryland state correctional and juvenile facilities. The Maryland Department of Health is working with the Maryland Department of Public Safety and Correctional Services and the Maryland Department of Juvenile Services to implement universal testing for residents/inmates/patients and staff of these facilities; and

4) Coordinate with private partners and retailers to increase testing statewide. In mid-May, Governor Hogan implemented an emergency order to authorize all of Maryland's licensed pharmacists to order and administer COVID-19 tests. In addition, CVS Health has launched 30 new COVID-19 test sites at select CVS Pharmacy drive-thru locations across Maryland. We are in discussions with CVS Health to expand our testing partnership through the fall. Additional retail partners include Rite-Aid and Walmart, who are operating 3 sites each in the state.

As Maryland learns more about the usage of point-of-care testing systems and establishes new partnerships with commercial and academic laboratories, we intend to make additional testing resources and locations accessible through our local partners. c.) Maryland is in the planning stages for a statewide serological test-based survey to estimate the extent of COVID-19 infection in Marylanders, with input from academic, hospital, and public health experts. We intend for this survey to be an efficient design adequate to permit estimates for overall population prevalence, and prevalence in highly affected and vulnerable sub-populations. We expect to commence testing no later than early July, with initial results to be available by early August. We intend to follow up with additional rounds of testing as necessary. Additional information can be provided once this survey design is complete and implementation is underway.

Maryland has contracted with Abbott Laboratories to use their Chemiluminescent immunoassay and has secured sufficient quantities of this test for at least the first two rounds of potential planned testing. In addition, we intend to work with private, academic, and community partners to link together any other serological efforts that may be taking place in Maryland. State public health laboratory is leveraging the use of two existing high capacity Abbott Architect instruments to perform large volumes of SARS-CoV serology testing using the Abbott IgG assay. d.) The Maryland Department of Health is in regular communication with local health officers about all aspects of the state's COVID-19 response efforts, including testing strategies and alignment of state goals with local goals. There is also daily contact with local jurisdictions and private partners to support local efforts by providing additional testing supplies, staffing or other logistics and supply (ex. PPE) needs where possible. Currently, the state is allocating regular shipments of collection kits and laboratory processing capacity to each local jurisdiction based on community need and population to be tested. This supply, with the volume expanded as requested by local health departments, will supplement any efforts spearheaded by local jurisdictions to expand overall capacity in the state.

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Since testing is a matter of not only the specimen collection and laboratory processing, the Maryland Department of Health is also ensuring that each of its contracted laboratories have robust processes in place for ordering of tests and resulting back to patients, providers, the state, and the CDC (the pre and post-analytical phases). There is regular communication with the laboratories' administration and operations to ensure that any issues that may arise prior to and after specimen analysis are corrected immediately.

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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*	200,000	300,000	300,000	600,000	600,000	600,000	600,000	600,000	3,800,000
Serology	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA	0
TOTAL	200,000	300,000	300,000	600,000	600,000	600,000	600,000	600,000	

*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)
Waldorf Vehicle Emission Inspection Program (VEIP) Testing Location	Drive-thru testing site	Quest	144	0	
Owings Mills Vehicle Emission Inspection Program (VEIP) Testing Location	Drive-thru testing site	Quest	288	0	
Hagerstown Vehicle Emission Inspection	Drive-thru testing site	Labcorp	144	0	

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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)
Program (VEIP) Testing Location					
Prince Frederick Vehicle Emission Inspection Program (VEIP) Testing Location	Drive-thru testing site	Labcorp	144	0	
Clinton Vehicle Emission Inspection Program (VEIP) Testing Location	Drive-thru testing site	Labcorp	144	0	
Hyattsville Vehicle Emission Inspection Program (VEIP) Testing Location	Drive-thru testing site	Labcorp	288	0	
Glen Burnie Vehicle Emission Inspection Program (VEIP) Testing Location	Drive-thru testing site	Labcorp	192	0	
Carroll County Agricultural Center Testing Site	Drive-thru testing site	Quest	192	0	

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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)
Six Flags America	Drive-thru testing site	Labcorp	1,400	0	
Columbia Vehicle Emission Inspection Program (VEIP) Testing Location (LHD managed)	Drive-thru testing site	Quest/Labcorp	288	0	
White Oak Vehicle Emission Inspection Program (VEIP) Testing Location (LHD managed)	Drive-thru testing site	Labcorp	288	0	
Druid Hill Park Testing Site	Community-based	Labcorp	144	0	
Clifton Park Testing Site	Community-based	Labcorp	144	0	
CVS (30 sites)	Drug store or pharmacy			0	
Rite Aid (2 sites)	Drug store or pharmacy			0	

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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)
Walmart (3 sites)	Drug store or pharmacy			0	
Skilled Nursing	Hospitals or clinical facility	CIAN/State Lab	2,800	0	High-risk medical patients and staff
Corrections	Other	ICMD	500	0	Inmates, officers and staff
Juvenile Services	Other	ICMD		0	Detainees, officers and staff
State facilities	Hospitals or clinical facility	State Public Health Lab		0	
Vulnerable/Homeless populations	Other	State Public Health Lab		0	
Assisted living facilities	Hospitals or clinical facility	CIAN/State Public Health Lab		0	
Federally Qualified Health Centers	Federally Qualified Health Center			0	
Hospital sites	Hospitals or clinical facility			0	
Urgent Care/Other providers	Hospitals or clinical facility			0	

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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)
Local Health Department	Community-based	Various	1,000	0	

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

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

a.) Maryland has made significant progress in expanding statewide testing capacity and will continue to expand testing capacity to achieve the daily testing target of 20,000 tests/day. These efforts include contracting with several laboratories to date, with further planned expansion of the state public health laboratory (SPHL) capacity. Currently, the Maryland Department of Health (MDH) maintains active agreements with four commercial laboratories, two of which are in-state, and two which are national firms. Maryland's overall median lab result turn-around time – a key “gating criterion” referenced by CDC – now stands at under 2 days. The increased laboratory capacity has enabled the state to establish over fifteen state and local health department-run community based testing sites, including at least four high volume sites, allocate additional testing supplies to local health departments to support community testing efforts, and universal testing in skilled nursing facilities and the state correctional system. b.) Maryland will continue to prioritize vulnerable and at-risk populations as part of expanded testing efforts. On April 5, 2020 and April 29, 2020, Governor Hogan announced that the state would focus additional testing resources on high-priority outbreaks and clusters, including nursing homes and poultry plants, as well as frontline health care workers and first responders at state facilities. In addition, on April 13, 2020, the state established facility response teams in coordination with the National Guard and HHS Defense Medical Forces to provide targeted assessment and testing support for assisted living facilities and group homes for individuals with disabilities and behavioral health conditions. The universal testing of skilled nursing homes is anticipated to be complete by the end of May. As further directed by Governor Hogan on May 20, 2020, universal testing efforts are underway with the Department of Public Safety and Correctional Services (DPSCS) and the Department of Juvenile Services (DJS) for their populations, including all staff.

A vulnerable population taskforce has been established to conduct outreach and testing for individuals who are homeless in coordination with homeless outreach agencies and local social services agencies. Testing has been made available to all first responders in the state in coordination with the Maryland Institute for Emergency Medical Services Systems (MIEMSS). Future initiatives include establishing additional partnerships with Federally Qualified Health Centers (FQHCs) and community-based organizations to provide greater outreach into underserved communities and populations that may have much less access to testing and other health services. MDH has long supported local health departments (LHDs) as the central public health authority in each of Maryland's 24 jurisdictions. MDH recognizes that the LHDs have a uniquely direct, granular and long-standing understanding of community needs and resources in their jurisdictions. MDH continues to encourage LHDs to use creative local partners and strategies to maximize testing accessibility in every community in Maryland, with special attention and focus on communities which are under-served and with high disease burden.

In addition to the multiple drive-through and walk-up testing sites across the State, MDH provides weekly allocations of test kits to every jurisdiction, in amounts stratified by population and burden of

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cases. MDH is pleased to be able to regularly offer to increase these allocations to any local jurisdiction requesting a greater supply. The LHDs then are able to offer testing in nonconventional community settings, including mobile sites. c.) To integrate the wide-ranging efforts supporting the testing of Marylanders for COVID-19 infection, the State of Maryland is utilizing an Incident Command System approach to form a Unified Area Command (UAC) to identify and resolve barriers to efficient testing as a cohesive whole. This effort builds on the collaborations established early in the pandemic response by the state epidemiology team, the state public health laboratory, local health departments, academic institutions, and other state agencies. This provides a systematic structure to engage, evaluate, and resolve barriers in a formalized multidisciplinary approach. One example of this collaborative approach is the establishment of drive through testing at VEIP locations, when the Maryland Department of Transportation (MDOT) provides the VEIP sites, while the Maryland National Guard provides logistics and operational support and local health departments provides clinical staffing and operational leadership.

Additionally, non-state or private entities can be seamlessly integrated into the UAC. Other UACs in place within the State already incorporate the Maryland Hospital Association into their workflows. The State continues to work with the Chesapeake Regional Information System for our Patients (CRISP), the state designated Health Information Exchange, and has established HL7 messaging data exchange between NEDSS, the State's infectious disease surveillance data management and reporting system, and CRISP so that COVID test result data can be presented via CRISP. Maryland requires all Maryland COVID-19 tests results (positive and negative) to be reported to NEDSS. Further integration with CRISP allows for test results all throughout the state from partners including clinicians, hospitals, pharmacies, insurers, and laboratories. By collecting both private and public testing results into one place, this information is then provided to the contact tracing efforts through the State's contract with the National Opinion Research Center to support the expansion of local contact tracing. We expect that these activities would be further enhanced through the resources that the UAC will bring together.

State Lab Viral Transport Media (VTM) Collection:

In response to the global shortage of VTM, the SPHL Director recruited a team of MDH Laboratory scientists who were experienced in making microbiological culture media and assigned them to making VTM. Beginning on March 26, 2020, the SPHL began making approximately 1,000 VTMs per week and has continuously ramped up production and is now making 5,000 VTMs per week. To date, the SPHL has produced 37,500 VTMs. To overcome specific testing supply chain problems the SPHL is running multiple SARS-CoV-2 RT-PCR detection testing systems and has cross validated several nucleic acid extraction procedures from multiple vendors.

Additionally, Maryland has contracted with several commercial laboratories to ensure redundancy in the supply and to alleviate supply chain issues. In addition to sample collection and processing, Maryland has set up several processes to ensure that results are communicated back to the appropriate parties.

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Laboratories submit results to the Department and to the state health information exchange, CRISP. Where applicable, the state ensures that patients tested have instructions to access the commercial laboratory's patient portal directly and has worked with the provider community to provide guidance and instructions on how to access all results through CRISP. The state has also set up several call centers to report results to providers from testing at community-based testing sites. d.) Maryland is in the planning stages for a statewide serological-test-based survey to estimate the impact of COVID-19 on Marylanders with academic, hospital, and public health experts. We intend for this survey to produce a high confidence interval and a low statistical margin of error with a high sample size utilizing the Abbott Laboratories Chemiluminescent immunoassay. The collection of samples will be determined by the serosurvey plan developed in conjunction with stakeholders and executed with partner hospitals, local agencies, and community organizations. We anticipate that this activity will occur in the next two months with results reported shortly thereafter. and to complete the first round of testing by July, and to follow-up with additional rounds of testing as necessary. Additional information will be provided on a rolling basis.

Maryland has an initial supply of the resources needed to perform tests on the Abbott Chemiluminescent immunoassay, and has contracted with Abbott to obtain the resources needed for additional follow-up testing in the following months. In addition, we intend to work with private, academic, and community partners to link together any other serological efforts that may be taking place in Maryland.

e.) Please see the earlier responses to these questions above. In addition, MDH's Office of Minority Health and Health Disparities is finalizing a community and communications plan similar to community outreach efforts on the Eastern Shore for the National Capital Region with additional expansion phases statewide. f.) Under Maryland's procurement laws, the State (a combination of the Maryland Department of Health, the Maryland Department of General Services, and the Maryland Department of Budget and Management) has entered into a combination of emergency procurements, commodity purchases, and agreements with suppliers and laboratories to acquire the necessary resources to expand testing. While the State has been pursuing these avenues from the start, the State must present those emergency contracts to the State's Board of Public Works for approval. These contracts include capacity building with private laboratories, additional testing resources from well-established laboratories who have their own supplies, and directly with suppliers to obtain resources for the state laboratory, hospitals laboratories, and academic laboratories within the State. By diversifying where the tests are processed and the resources used to conduct those tests, the State is actively planning to avoid shortages and bottlenecks like those faced at the outset of the COVID-19 pandemic response.

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

BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Number of additional* staff to meet planned testing levels		3 Public Health Laboratory Scientists. 1 Public Health Laboratory Scientist Supervisor. 1 Information Technology position.	3 Public Health Laboratory Scientists. 1 Public Health Laboratory Scientist Supervisor	3 Public Health Laboratory Scientists. 1 Public Health Laboratory Scientist Supervisor	3 Public Health Laboratory Scientists	1 Public Health Laboratory Scientist			0
FOR DIAGNOSTIC TESTING									
How many additional* testing equipment/ devices are needed to meet planned testing levels? (provide an estimated	2 Biomerieux EMAG RNA Extraction Platforms								0

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BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
number, and include platform details in narrative above)									
Volume of additional swabs needed to meet planned testing levels ⁺⁺	300,000	300,000	300,000	600,000	600,000	600,000	600,000	600,000	3,900,000
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels ⁺⁺	225,000	225,000	225,000	500,000	500,000	500,000	500,000	500,000	3,175,000

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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)	300000	300000	300000	600000	600000	600000	600000	600000	
FOR SEROLOGIC TESTING									
Number of additional* equipment and devices to meet planned testing levels	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA	0

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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)	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA	

* 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.