

ELC ENHANCING DETECTION: USVI TESTING PLAN

2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	USVI
Population Size:	

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

a) How you will maximize the use of testing platforms (with an indication of which ones are high throughput), venues, and expanded workforce across your jurisdiction (e.g. public health labs, private, hospital, commercial, academic, etc.) to rapidly scale testing to accommodate an increased demand for SARS-CoV-2 tests, including utilizing point-of-care or other rapid result testing for local outbreaks?

The availability of high complexity laboratories with high-throughput testing and molecular testing is limited in the Territory but capable of meeting the planned testing demands. The DOH of public health laboratory on St Croix has multiple testing platforms to conduct the CDC test, Hologic Panther, Hologic Fusion, GeneXpert, and Biofire tests. Both hospitals in the Territory have the capacity to conduct the Abbott ID Now and GeneXpert tests. Schneider Regional Medical Centre hospital on St Thomas also has the capacity to conduct Hologic Panther testing. Two commercial laboratories are also expected to have testing capacity for high-throughput antibody testing. Both laboratories have Siemens Atletica instruments, one also has Abbott Architect, and the other plans to bring on Roche Cobas. Additional High-throughput testing is not available or planned in the Territory. Private providers, at their discretion, may eventually offer rapid later flow tests.

Due to the relatively small population base, approximately 105,000 persons, all symptomatic cases and their contacts have been able to be tested with support from CDC. More recently this is entirely being conducted locally. These supplies have been difficult to obtain but the DOH has 5000 tests currently on hand and will work closely with Hologic and the Federal Government to procure additional supplies as warranted by testing demand. At current testing rates these supplies are likely to last up to 90 days. The expected testing demand in USVI to maintain testing of all symptomatic cases and contacts is extremely low in comparison to other jurisdictions. The DOH also has the capacity to perform Hologic Fusion testing, which has a lower user base nationally, and could provide for contingency testing if those supplies become available. These have been purchased but the Territory has never been allocated these resources.

The DOH Public Health laboratory and primary testing sites have the necessary capacity and redundancy needed under the current environment of supply allocations as determined by the Federal Government. Thus far, the Territory has been able to use two drive-thru testing locations for all symptomatic individuals and contacts. MOUs are also in place to add additional sites if warranted. The two Federally Qualified Health Centers in the Territory are a priority because of their low-income and minority populations. Testing expansion to two clinical laboratories, with the equipment already in place and test verified, will allow for the DOH to quickly ramp up additional epidemiological surveillance and antibody

ELC ENHANCING DETECTION: USVI TESTING PLAN

tests. The DOH will initially purchase 10,000 of these tests for surveillance and potential at-risk populations. The DOH has sufficient funding to maintain testing for all symptomatic individuals and contacts for the foreseeable future. However, these successes are at risk if supply allocations to the Territory are not improved.

b) Detail your approach to provide testing at non-traditional laboratory sites (e.g., retail sites, community centres, residential medical facilities, or pharmacies).

The Territory is geographically small and non-traditional laboratory sites have not been necessary. The two drive-thru facilities have been sufficient. The Abbott ID Now instruments provided to the Territory are located at the two hospitals in order to ensure rapid testing for this critical population. If a surge in testing occurs additional sites may be added; however, we anticipate that the addition of two private clinical laboratories will be sufficient.

c) Describe your strategy for serology testing, if applicable.

The Territory will maximize FDA approved high throughput serological testing by partnering with the two laboratories on island with the necessary equipment and assurances from the vendors of sufficient production supply. The DOH is initially purchasing 10,000 tests to be performed on this equipment and one of the laboratories already has 2000 tests on hand and been assured that 20,000 tests is available for purchase by the vendor. The DOH also has automated serology testing equipment, two Dynex DS2 machines, for ELISA format serology tests that could be used as a contingency once FDA authorized tests become available.

To date, no additional private providers in the Territory have FDA authorized rapid point of care antibody tests and there are only 69 CLIA laboratories in the Territory. A small minority of these providers are expected to offer testing and the DOH is conducting outreach to determine the total number there are planning testing for their clients. Currently, the Department of Health has been working with two clinics/labs and CLIA to validate a non-FDA approved point of care test that the providers purchased.

The Department of Health Epidemiology Division will initially direct the use of serology tests. will begin using serological surveillance for specific at risk groups including healthcare workers. Dependent upon the rates found these may be expanded in a phased approach to skilled nursing facility works, other first responders, long term care, senior living, persons over 65 and or with high risk chronic disease and immune disorders. If rates remain low widespread spread serological surveillance is not warranted. We

ELC ENHANCING DETECTION: USVI TESTING PLAN

anticipate that private commercial laboratories and providers will eventually have access to robust serological tests and provide this service to the community.

d) Describe how you will communicate, collaborate and coordinate with the broad testing community within your state to ensure alignment in approach and progress toward jurisdictional goals. Plan should include regular outreach to testing partners to monitor test kits, supply, and reagent inventory and staffing levels.

Fortunately due to the size of the Territory, there is a not broad testing community or need within the jurisdiction that requires extensive resources for effective communication. Communication is easily coordinated even on a daily basis. There are only two hospitals, two FQHCs, and two private clinical laboratories with the capability of high-throughput testing. There are only approximately 40 providers approved by CLIA for waived testing and the vast majority of these are unlikely to ever offer testing. CLIA has been informing the DOH and communication has begun as soon as any provider requests the ability to perform COVID-19 waived testing.

The Department of Health is documenting supply levels for the public health laboratory and hospitals on a daily basis. Hologic testing supplies and Abbott ID Now supplies are being supplied to the hospitals. Initial serological tests will be purchased from the two clinical labs and that inventory maintained for surveillance as directed by the DOH.

ELC ENHANCING DETECTION: USVI 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*	1,700	1,700	1,800	1,800	2,000	2,000	2,000	2,000	15,000
Serology	0	1,800	1,800	1,800	1,800	1,800	1,800	1,800	12,600
TOTAL	1,700	3,500	3,600	3,600	3,800	3,800	3,800	3,800	

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)
DOH Public Health Laboratory	Public health lab		375			Symptomatic individuals and contact tracing.
DOH Public Health Laboratory	Public health lab		375			Symptomatic individuals and contact tracing. Backup testing if allocations for Hologic Panther change.
DOH Public Health Laboratory	Public health lab		30			Symptomatic individuals and contact tracing. Backup testing if allocations for Hologic change.

ELC ENHANCING DETECTION: USVI 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)
DOH Public Health Laboratory	Public health lab		12			Symptomatic individuals and contact tracing. Rapid testing providing availability.
DOH Public Health Laboratory	Public health lab		24			Symptomatic individuals and contact tracing. Rapid testing providing availability.
DOH Public Health Laboratory	Public health lab			100		Surveillance at request of Epidemiology Division. Backup and verification of commercial testing.
Schneider Regional Medical Center	Hospitals or clinical facility		375			Symptomatic individuals and contact tracing.
Schneider Regional Medical Center	Commercial or private lab		24			Symptomatic person presenting to hospital. Symptomatic staff and visiting healthcare staff.

ELC ENHANCING DETECTION: USVI 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)
Juan Luis Medical Center	Commercial or private lab		24			Symptomatic person presenting to hospital. Symptomatic staff and visiting healthcare staff.
Clinical Laboratory Inc	Commercial or private lab		40			Symptomatic person presenting to private clinical lab.
Clinical Laboratory Inc	Commercial or private lab			1,000		Private test requests and tests purchased by DOH. Test purchased by DOH for high risk healthcare, long-term care, and other upon request from Epidemiology Division.
Clinical Laboratory Inc	Commercial or private lab			1,500		Private test requests and tests purchased by DOH. Test purchased by DOH for high risk healthcare, long-term care, and other upon request from Epidemiology Division.
St Thomas Clinical Reference Laboratory	Commercial or private lab			1,500		Private test requests and tests purchased by DOH. Test purchased by DOH for high risk healthcare, long-term care, and other upon request from Epidemiology Division.

ELC ENHANCING DETECTION: USVI 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)
St Thomas Clinical Reference Laboratory	Commercial or private lab			1,000		Private test requests and tests purchased by DOH. Test purchased by DOH for high risk healthcare, long-term care, and other upon request from Epidemiology Division.+A9:L70A2:L70A1:L70B9A1:L70B1:L70A1:L70B1:L70

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.

Thus far, due to the small size of the jurisdiction and limited molecular and high-throughput testing available all test requests for symptomatic persons and contact tracing has been conducted through the Department of Health. Specimens were initially submitted to CDC but are not conducted entirely within the Territory. Only 13% of tests have been conducted by a large stateside commercial laboratory. All of those positive results are reported to the DOH for follow-up. The only other testing for symptomatic individuals has been conducted at two local hospitals in which the DOH provides the test supplies. The DOH has also provided control specimens and worked with private providers towards test verification for those intending to perform point of care serological testing.

a) Describe how the health departments will directly expand testing capacity through their public health labs, contracts, partnerships, and other arrangements (e.g. adding testing capacity in local health departments, contracting with new labs, partnering with academic and community-based organizations, establishing drive-thru testing sites, etc.). Provide specifics about planned expansions of existing capacity, including procurement of new testing equipment or device platforms.

The Territory does not require expanded testing capacity for symptomatic persons and their contacts. Additional equipment and testing is not warranted and not a judicious use of resources. The Territory has two instruments with a maximum throughput of 1000 tests per day, each. The Territory has only received 125 specimens a day maximum and can easily accommodate a surge in this testing. The DOH maintains two drive-thru testing sites and will expand if a surge occurs in the future. The Territory only has two hospitals that receive severe cases and both are equipped for rapid testing. The Health Department is well-equipped and has over a half a dozen platforms for testing. Supplies are now currently available to conduct testing on the most efficient of these.

The Territory is currently working to expand serological testing capacity and will partner with the only two commercial laboratories in the Territory with the equipment to conduct this testing.

b) How testing needs of vulnerable and at-risk populations will be prioritized, including the elderly, disabled, those living in congregate settings including nursing homes and prisons, racial and ethnic minorities, healthcare workers, and among persons experiencing homelessness.

ELC ENHANCING DETECTION: USVI TESTING PLAN

The Territory has been fortunate that there has been sufficient testing capacity available to test all symptomatic persons and their contacts. If someone is symptomatic in any at-risk population, or any population for that matter, they are tested without the need for any prioritization.

The DOH intends to conduct some serological surveillance on these populations should cases begin to be identified. The seroprevalence will initially be performed on the highest risk group for infection, hospital healthcare staff. Surveillance for additional groups will be conducted as warranted.

All high risk populations and staffing for vulnerable populations have access to the Department of Health through the COVID-19 hotline. Regular meetings between the DOH and those responsible for managing these populations are conducted regularly.

c) How barriers to efficient testing will be identified and overcome, including those related to underutilization of available assets and supply-chain difficulties, and considerations with end-to-end logistics of testing (from sample collection to reporting to public health and CDC).

Supply levels are monitored daily by the DOH so that any challenges can be addressed quickly. The size of the Territory and limited number of providers has limited the number of logistics that may be encountered elsewhere. However, the geographical isolation of the US Virgin Islands, small population size, and limited case numbers has presented challenges for supply allocations. The DOH will continue to work with CDC, HHS, and FEMA to ensure that the Territory is able to maintain those supplies and maintain the success achieved thus far.

d) Describe the strategy for serology testing through the public health labs, if applicable, including specific platforms intended to be used.

In an effort of expediency the DOH will rely on two local clinical laboratories to conduct public health surveillance activities requiring serological testing. The DOH has worked with these providers to provide control specimens and to verify these FDA test platforms. At least 10,000 tests will initially be purchased for the purposes and their usage will be directed by the DOH Epidemiology Divisions. In addition, the DOH Public Health laboratory will develop local capacity using existing instrumentation once FDA approved ELISA format tests become available. The DOH laboratory has two automated Dynex DS2 instruments, each capable of testing two 96-well plates of specimens concurrently every 2-3 hours.

e) Describe the health department's plan for resource utilization and how the jurisdiction will manage testing and alignment with SARS-COV-2 community mitigation policies, including sentinel surveillance for vulnerable populations.

ELC ENHANCING DETECTION: USVI TESTING PLAN

The testing plan presented here is developed in alignment with a broader USVI Surveillance and Testing Surge Plan for Coronavirus Disease. It is critical that the Territory maintains the capacity to test every symptomatic individuals and their contacts.

Additional sentinel surveillance for vulnerable populations will be directed by the Epidemiology Division and conducted as needed. At low transmission the volume and frequency of testing is not yet warranted.

f) Describe the health department's plan to expedite and streamline procurement, hiring, and onboarding 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)

The DOH is requesting funding to recruit a lab manager to assist in procurement and the additional manpower needed to facilitate a surge in testing. Additional laboratory staffing is not anticipated provided testing supplies are available for high-throughput instrumentation. The DOH will be requesting a single additional laboratory technician to be staffed at Schneider Regional Medical Center to provide additional personnel for Hologic Panther testing.

ELC ENHANCING DETECTION: USVI 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	0	2	0	0	0	0	0	0	2
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	0	0	0	0	0	0	0	0
Volume of additional swabs needed to meet planned testing levels ⁺⁺			1,800	1,800	2,000	2,000	2,000	2,000	11,600
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels ⁺⁺			1,800	1,800	2,000	2,000	2,000	2,000	11,600
Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher)			Hologic 2500 per month	Hologic 2500 per month	Hologic 2500 per month	Hologic 2500 per month	Hologic 2500 per month	Hologic 2500 per month	
FOR SEROLOGIC TESTING									

ELC ENHANCING DETECTION: USVI TESTING PLAN

BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Number of additional* equipment and devices to meet planned testing levels	0	0	0	0	0	0	0	0	0
Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher)		Serology Tests 1800							

* 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.