

ELC ENHANCING DETECTION: PUERTO RICO TESTING PLAN

2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	Puerto Rico
Population Size:	3,200,000

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

a)

The Puerto Rico Department of Health (PRDOH) established a State Communication Plan (SCP) with external laboratories (private, reference and academic) to facilitate and track information exchange regarding their testing capacity, testing platforms and inventory of reagents, kits and materials. This information will help the PRDOH to strategize with external laboratories while maximizing the use of the different testing platforms available around the island. Most reference laboratories have high throughput instrumentation such as Roche Cobas 6800, Abbott m2000 Systems, and Hologic Panthers. In order to maximize the use of these platforms and those available at the PRDOH, the SCP provides the information needed to rapidly accommodate increased demand for testing in the event of local outbreaks. In such document the information regarding available tests by location will be readily available.

Being able to map the location of these external laboratories with high throughput instrumentation, as well as Point-of-Care testing platforms (e.g. Abbott ID NOW), will permit a rapid referral of samples for immediate testing. This will decrease the turnaround time of results allowing for a rapid response, which will lead to the implementation of the appropriate control measures in order to halt the spread of the virus in local hotspots.

Additionally, mapping the island-wide testing capacity will provide visual information of locations with small to no testing capacity. In this regard we can prioritize the deployment of Clinical Outreach Teams (COT) to collect samples from these locations for immediate analysis at partner private or reference laboratories, and at the Public Health Laboratories (see more about COT below).

b)

Plans to provide testing at non-traditional laboratory sites currently include community centers, municipal coliseums and convention centers, as well as drive-through facilities for sample collection. The PRDOH has established drive-through testing sites distributed around the island for first responders and communities at-risk, which are managed by the PRDOH staff and the National Guard.

In addition, we will create five Clinical Outreach Teams, each one composed of two nurses and two data entry staff. These COT will help impact communities that can't benefit from the drive-through facilities due to accessibility limitations. A PRDOH COT coordinator will coordinate with municipal governments and community leaders to identify testing sites within their communities to impact their vulnerable and underserved groups such as the homeless shelters, food processing plants, food handlers, retail, correctional facilities, nursing homes, and essential public workers (e.g. water treatment plants, energy plants, etc.). These teams will then be mobilized around the island to collect samples from members of these communities, in a volunteer basis, and transport the samples to the PRDOH Public Health

ELC ENHANCING DETECTION: PUERTO RICO TESTING PLAN

Laboratories (PRPHL) for analysis. In case of distant communities, we will partner with PRDOH regional laboratories for sample storage for next day delivery to the PRPHL.

The plan proposes the use of rapid molecular testing platforms (such as the Abbott ID NOW) and the COT location assignments will change daily in order to impact as many vulnerable communities as possible. These test results will allow each regional epidemiologist to identify localized outbreaks and implement measures to prevent further spread of the virus in the affected communities. With the COT, PRDOH plans to impact the non-traditional laboratory sites mentioned above and surpass the 2% of population test goal (64,000 tests/month).

c)

Serological tests will be used at the correctional facilities to conduct a second screening among that population which consists of 10,000 inmates. Also, these tests will be used according to the new Executive Order at the airport for the screening of symptomatic (fever, cough and breathing difficulty) travelers arriving to the Island. The PRDH supports other efforts distributing serological tests for special projects of the PR College of Medicine and supplies medical facilities (hospitals, clinics) around the Island as well as clinical laboratories.

d)

Our current plan includes drive-through testing sites around the island that are managed by PRDOH employees. The points of contact (POC) oversee daily operations and communicate with personnel (nurses, MTs, data entry, etc.) to assure that sample collection and outsourcing to the private partner laboratory occurs at the end of each day. The POC from each tent communicates the quantity of samples taken and what communities were impacted (e.g. first responders, school employees, elderly, etc.). This information along with test results allow us to strategize next steps towards achieving our testing goals.

In addition, partnerships with private laboratories on the island have been established and concurrent meetings are scheduled to discuss number of tests performed, reagents and supplies inventory status and their projected capacities for the upcoming months. For the latter, a State Communication Plan was established where external laboratories will provide the information to the Division of Laboratories of the Auxiliary Secretariat for Regulation and Accreditation of Health Facilities (SARAFS, for its Spanish acronym).

ELC ENHANCING DETECTION: PUERTO RICO 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*	7,700	10,280	154,420	154,420	154,420	154,420	241,100	241,100	1,117,860
Serology	39,065	40,000	84,000	84,000	84,000	84,000	84,000	84,000	583,065
TOTAL	46,765	50,280	238,420	238,420	238,420	238,420	325,100	325,100	

*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)
Puerto Rico Department of Health	Public health lab	Biological and Chemical Emergencies Laboratory	350	0	Hospitalized patients.
Puerto Rico Department of Health	Public health lab	Institute of Public Health Laboratories of Puerto Rico	114	0	First responders (healthcare and non-healthcare workers); correctional facilities, school workers, nursing homes, retail, homeless, food processing plants, food handlers, public essential service workers.

ELC ENHANCING DETECTION: PUERTO RICO TESTING PLAN

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)
Puerto Rico Department of Health	Public health lab	Institute of Public Health Laboratories of Puerto Rico	256	0	First responders (healthcare and non-healthcare workers); correctional facilities, school workers, nursing homes, retail, homeless, food processing plants, food handlers, public essential service workers.
Puerto Rico Department of Health	Public health lab	Institute of Public Health Laboratories of Puerto Rico	256	0	First responders (healthcare and non-healthcare workers); correctional facilities, school workers, nursing homes, retail, homeless, food processing plants, food handlers, public essential service workers.
Puerto Rico Department of Health	Public health lab	Institute of Public Health Laboratories of Puerto Rico	1,500	0	First responders (healthcare and non-healthcare workers); correctional facilities, school workers, nursing homes, retail, homeless, food processing plants, food handlers, public essential service workers.
Puerto Rico Department of Health	Drive-thru testing site	Quest Reference Laboratory	150	0	First responders (healthcare and non-healthcare workers); correctional facilities, school workers, nursing homes, retail, homeless, food processing plants, food handlers, public essential service workers.
Laboratorio Cl. Toledo	Commercial or private lab		820		General population

ELC ENHANCING DETECTION: PUERTO RICO TESTING PLAN

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)
Laboratorio Cl. Toledo	Commercial or private lab		313		General population
Laboratorio Cl. Toledo	Commercial or private lab		1		General population
Inno Diagnostics -PSM	Commercial or private lab		139		General population
Inno Diagnostics -PSM	Commercial or private lab		131		General population
Laboratorios Borinquen	Commercial or private lab		351		General population
Laboratorio Cl Martin	Commercial or private lab		50		General population
Lab Cl. Y Molec. Southern Pathology	Commercial or private lab		137		General population
Immuno Reference Lab	Commercial or private lab		219		General population
Immuno Reference Lab	Commercial or private lab		198		General population

ELC ENHANCING DETECTION: PUERTO RICO TESTING PLAN

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)
Hato Rey Pathology Associates	Commercial or private lab		133		General population
Laboratorio Clínico Noy	Commercial or private lab		258		General population
CorePlus Servicios Clínico y Patológicos	Commercial or private lab		192		General population

ELC ENHANCING DETECTION: PUERTO RICO 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.

a)

The State Testing Plan includes the PRDOH PRPHL (Institute of Public Health Laboratories and the Biological and Chemical Emergencies Laboratory), private reference laboratories and academic labs. The expected testing capacity of the PRDOH for July 2020 is 24,420 diagnostic tests/month and for the conglomerate of external laboratories (private, reference and academic labs) is approximately 130,000 diagnostic tests/month, for a total of 154,420 tests per month (4.8% of the population). In order to increase capacity at the PRDOH laboratories by September 2020, we plan to acquire new, high throughput testing platforms for the PRPHL (e.g. two Hologic Panther, >1,500 samples/day; one GeneXpert 16 modules, >300 samples/daily), expand on rapid molecular testing using Abbott ID NOW platforms in the PRPHL facilities and will explore the implementation of mobile testing units for rapid result testing for local outbreaks and drive-through sites across the island.

The following testing platforms and outsourcing capacity are available in the PRDOH laboratory facilities: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel run in ABI 7500 Fast DX systems (12,240 tests/month), Abbott ID NOW (7,680 tests/month), and outsourcing to a private reference lab (4,500 test/month). We plan to add new testing platforms by September 2020, the Cepheid GeneXpert 16-module system (7,680 tests/month) which will increase the PRDOH monthly testing capacity to 66,100 tests. We are also requesting the acquisition of a Roche MagNA Pure 96 extraction platform and two additional ABI 7500 Fast Dx systems, which will increase our testing capacity by an additional 5,220 tests/month with the CDC Diagnostic Panel.

The PRPHL has a Hologic Tigris that will be upgraded to two Hologic Panther platforms to include the SARS-CoV-2 diagnostic panel; this high throughput platform has the capacity to process 45,000 tests/month, thus increasing monthly testing capacity at the PRDOH to 116,320 tests/month (3.6% of population). The testing capacity of the PRDOH including external testing facilities will be of approximately 246,320 tests/month which accounts for 7.7% of the population. However, it is expected that the projected number of samples processed monthly will be below the testing capacity due to reagents and materials allocation from manufactures. Nonetheless, we expect to test over the 2% population goal from July through December of 2020.

To reach the proposed testing capacity at the PRDOH, we plan to expand the laboratory workforce with seventeen medical technologists, seventeen laboratory assistants, fifteen data entry staff, and two IT Specialists for the laboratory information management system (LIMS), STARLIMS PH12.0 technical assistance and maintenance.

b)

The PRDH will conduct serological and molecular testing in the long-term care facilities in the next three to four months. For the population of older adults living in households, PRDH will engage in collaborations with health insurance companies and municipalities to reach this population. Approximately, 900,000 adults are 65 or older.

ELC ENHANCING DETECTION: PUERTO RICO TESTING PLAN

During March 2020, a baseline serological survey was done in all correctional facilities in Puerto Rico. In that baseline survey approximately 8,600 inmates and custodian guards were tested. In that baseline survey approximately 8,600 inmates and custodian guards were tested. A second screening will be conducted at the correctional facilities.

The first line in defense of COVID-19 is our first responders. These professionals are consistently considered high risks groups, especially for the exposure of symptomatic and asymptomatic patients. An effort had been made throughout Puerto Rico doing testing sites to these professionals, we plan to continue with the effort in the next months.

Other susceptible groups like HIV patients in Puerto Rico's population will be explored to extend the scope of Puerto Rico's testing in the next months.

With the collaboration of epidemiologists at the municipal level, testing needs of other vulnerable populations will be identified.

c)

We created a COVID-19 Laboratory Response Team composed of PRDOH laboratory staff with a designated laboratory administrator and response team leads that oversees laboratory day to day operations. These response leads evaluate testing capacity, inventory of reagents, supplies and consumables for each testing platform on a daily basis to assure that resources are being maximized at the PRDOH. The Laboratory Administrator oversees the sample collection at the central drive-through, transportation of samples to the PRPHL or the partner private laboratory and reporting of test results. We have tasked the Laboratory Quality Manager with reporting the number of samples tested and their results daily to the CDC. In the case of external partner laboratories, we have established a State Communication Plan where we request information about materials and reagents allocation from these laboratories on a monthly basis. This information has helped us identify reagent allocation as the most probable challenge we will face in our efforts to carry out the State Plan for Testing.

One way to mitigate this obstacle that may arise in terms of acquiring reagents and supplies from any specific manufacturer is ensuring access to multiple different testing platforms throughout the island. We have achieved this by identifying and establishing partnerships with external laboratories with high throughput testing capabilities and including them in our State Plan for Testing. By doing this, we have established access variety of testing platforms between the PRPHL and external laboratories, such as: Roche Cobas 6800, Abbott ID NOW, Abbott m2000 Systems, and Hologic Panthers, Cepheid GenXpert and ABI 7500 Fast Dx.

d)

There are no plans to perform serology testing at PRODH PRPHL as these are tasked to perform diagnostic testing.

e)

ELC ENHANCING DETECTION: PUERTO RICO TESTING PLAN

Materials for sample collection are being distributed in hospitals around the Island by the PRDH. This strategy supports the surveillance of the population of PR. Also, the clinical outreach teams will collect samples around the Island in collaboration with the municipalities in order to reach vulnerable populations.

f)

PRDOH is implementing a strategy to assure that we have the necessary workforce to manage all activities for the COVID-19 ELC supplements, which include hiring dedicated staff for ELC only activities in the following offices: Purchasing Office, Finance Office, Contracts Office (for onboarding processes), and Budget Office. The plan proposes to assign dedicated staff for the ELC supplement grants to the offices mentioned above to speed up processes which have been slow in the past. This strategy has been used with the Hurricane Crisis Cooperative Agreements in the PRDOH and has shown to be valuable in the acquisition of the necessary equipment, reagents, supplies, etc. in less time than usual, providing a mechanism to achieve the goals of our plan in the time proposed.

ELC ENHANCING DETECTION: PUERTO RICO 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	2	4	28	28	25	0	0	0	87
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)	1	2	1	4	0	0	0	5	13

ELC ENHANCING DETECTION: PUERTO RICO TESTING PLAN

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 ⁺⁺	5,000	5,000	32,100	32,100	72,600	72,600	72,600	78,360	370,360
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels ⁺⁺	5,000	5,000	32,100	32,100	72,600	72,600	72,600	78,360	370,360

ELC ENHANCING DETECTION: PUERTO RICO TESTING PLAN

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)			90/day - GeneXpert Xpress; 68/day - ID NOW	256/day - GeneXper Xpress; 68/day - ID NOW	256/day - GeneXpert Xpress; 68/day - ID NOW; 1,500/day - Hologic Panther	256/day - GeneXpert Xpress; 68/day - ID NOW; 1,500/day - Hologic Panther	256/day - GeneXpert Xpress; 68/day - ID NOW; 1,500/day - Hologic Panther	256/day - GeneXpert Xpress; 68/day - ID NOW; 1,500/day - Hologic Panther	
FOR SEROLOGIC TESTING									
Number of additional* equipment and devices to meet planned testing levels	39,065	40,000							79,065

ELC ENHANCING DETECTION: PUERTO RICO TESTING PLAN

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)									

* 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.