

ELC ENHANCING DETECTION: NEW YORK CITY TESTING PLAN

2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	New York City
Population Size:	8.5 million

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

New York City is committed to ensuring that all New Yorkers have appropriate access to SARS-CoV-2 testing. Testing capacity has been built and will continue to build on a collaborative approach between the Department of Health and Mental Hygiene (DOHMH) and the NYC public hospital system, NYC Health + Hospitals (H+H), which includes a system of 11 acute care hospitals and a network of Federally Qualified Health Care (FQHC) clinics. Capacity is currently at over 20,000 tests per day (May) and is expected to reach 50,000 tests per day by the end of August.

The NYC DOHMH Public Health Laboratory (NYC PHL) was one of the first labs in the country to offer SARS-CoV-2 clinical diagnostic testing and continues to provide and expand on this testing capacity. NYC PHL has brought the CDC and NYS FDA EUA assays and the Cepheid XpertXpress assay online, and will on-board the Hologic Panther TMA assay within the next several weeks (awaiting allocated reagents). A Roche COBAS 6800 instrument is expected to arrive within the next months and will be on-boarded for testing upon arrival. Ensuring that multiple platforms are available for all steps in testing mitigates issues with supply chain. Multiple extraction methods for the NYS and CDC assays have been verified for use, and multiple high-throughput platforms will be available. Existing testing instruments and platforms have been and will be leveraged to increase capacity and make the most efficient use of the expertise of existing staff as well as space, equipment, and ancillary supplies that were already available in the laboratory. To broaden capacity and to mitigate some of the impact of collection kit and health care worker personal protective equipment shortages, the NYC PHL has validated the use of alternate specimen types, such as nasal swabs and saliva, using alternate collection kits (like swabs and media designed for sexual health testing) for these tests. Nasal swabs and saliva can be self-collected in a “light touch” medical setting.

DOHMH and the NYC PHL are partnering with contracted medical teams to collect specimens at shelters; testing is performed at PHL and results reported within 24 hours of specimen collection. These results are used to inform clinical care of shelter clients and to inform isolation strategies to mitigate outbreaks in this setting. Point of care-format tests including the Quidel Sofia2 and Abbott ID NOW will be leveraged by NYC PHL in congregate settings serving vulnerable populations in a “strike team” format to address and mitigate acute outbreaks. These platforms may also be used to rapidly screen at intake in congregate settings to ensure rapid isolation of positive clients (with appropriate reflexive testing algorithms in place).

The NYC PHL will open nine “COVID Quickie Labs” centered at existing DOHMH Sexual Health Clinics, where patients can visit a co-located COVID Express site (“COVID Express x Quickie Lab”), self-collect

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specimens for testing, and receive same-day COVID test results via a patient portal. DOHMH clinic sites provide a welcoming environment to all, and offer services to patients regardless of immigration or insurance status. They are recognized as safe places for care to the communities they serve. The existing Chelsea Sexual Health Express and Quickie Lab that usually provide rapid sexual health screening and chlamydia and gonorrhea testing will become the first of the nine COVID Express x Quickie Lab sites. The eight new Quickie Labs, housed at the eight other DOHMH Sexual Health Clinic facilities, will be leveraged for SARS-CoV-2 during this emergency, and will become sexual health testing sites when the increased capacity for SARS-CoV-2 testing is no longer needed. The infrastructure to “activate” these Express x Quickie Labs to testing sites for any public health emergency in the future will remain and enable rapid and robust increase in capacity to respond. A tenth site, in Staten Island, is planned to ensure presence in all five boroughs.

The NYC PHL is also partnering with the NYC Office of the Chief Medical Examiner (OCME) to test all (approximately 8000) medical examiner cases in the next year. This will enable deaths that occur outside medical facilities to be appropriately classified as COVID-related is positive. These specimens are collected from the nasopharynx using easily obtainable swabs designed for sexual health testing specimen collection that were validated at NYC PHL for use for this testing using the NYS EUA assay. Cadaveric specimens will also be validated for testing using additional platforms (Cepheid) to ensure redundancy and mitigate potential supply chain issues.

Note that all test results generated at PHL and at the COVID Quickie Labs will be immediately electronically reported to the health department as well as to CDC through PHLIP reporting. In addition, viral whole genome sequencing will be performed on specimens from all positive patients. This data will be used to track the virus through NYC and will be critical while in suppression mode to determine if new cases represent resurgence of previously circulating virus or new introduction of virus into the NYC population.

In addition to public health laboratory-based testing, the city is leveraging new contracts between H+H and multiple commercial clinical laboratories as outlined in the table below to provide testing to New Yorkers in the community. Contracts specify turn-around times for testing of no more than 48 hours from receipt at the contracted lab. A specific contract is being put into place to provide specimen collection and testing services for residents of nursing homes.

Staff have and will continue to be hired at the NYC PHL to expand capacity through expansion of operating hours (the NYC PHL has moved to operating 2-3 shifts per day, 7 days a week) and expansion of sites. Additional staff are being hired through H+H to operate collection sites in the community, including “pop-up” specimen collection sites in schools, cultural centers, public recreation centers, houses of worship, and in tents and trailers set up in empty lots.

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At this time, the focus of serology testing in NYC is in the context of serosurveys of health care workers and first responders and other specifically targeted groups. Serology testing is available to the public through H+H. In June, DOHMH will launch a serosurvey as part of a population-based COVID cross-sectional survey, , aimed to reach 1,000 participants between June to September 2020, with plans to repeat during subsequent waves depending on the status of the outbreak. All other serosurveys done in NYC to date have used convenience samples, so this project will enable a more accurate estimation of the SARS-CoV-2 seroprevalence in NYC, and the serology testing will be performed at the NYC PHL. In addition, other specific serosurveys will look at seroprevalence in specific populations, including congregate settings, and to assess transmission in a characterized university community population.

DOHMH regularly communicates with the broad NYC clinical community about SARS-CoV-2 testing through weekly provider webinars (also attended by clinical laboratory leadership), Health Alert Network communications, and “Dear Colleague” newsletters. In addition, the NYC PHL regularly communicates with the NYC clinical laboratory network, often through the PHEP-funded Sentinel Laboratory Trainer, through regular email communications. H+H will continue to communicate through the network of contracted laboratories regarding supplies required for testing. NYC teams, with input from DOHMH and H+H, are working to solidify supply chains for collection kits and other supplies needed for testing.

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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*	450,000	1,120,000	1,400,000	1,400,000	1,800,000	1,800,000	1,800,000	1,800,000	11,570,000
Serology	230,000	90,000	105,000	200,000	200,000	200,000	200,000	200,000	1,425,000
TOTAL	680,000	1,210,000	1,505,000	1,600,000	2,000,000	2,000,000	2,000,000	2,000,000	

*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)
New York City Public Health Laboratory	Public health lab	NYC PHL	2,670	3,000	Congregate settings (including shelters, vulnerable populations, nursing homes, etc.), hospitals without other access to testing, underserved populations; population-based serosurveys, serosurveys in specific populations NOTE: Point of care format test capacity is not included. Quidel Sofia 2 and Abbott ID NOW platforms available.

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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)
NYC PHL COVID Quickie Labs (multiple sites)	Public health lab	COVID Quickie lab sites	5,000		Multiple sites in underserved neighborhoods co-located with other health department services, people without other access to testing
H+H Hospitals, Clinics, and Testing Sites	Hospitals or clinical facility	BioReference	10,000	100,000	elderly, racial and ethnic minorities, healthcare workers, staff for congregate settings, essential workers, first responders, contacts of positive COVID people
H+H Hospitals, Clinics, and Testing Sites	Hospitals or clinical facility	Quest	15,000		elderly, racial and ethnic minorities, healthcare workers, staff for congregate settings, essential workers, first responders, contacts of positive COVID people
H+H Hospitals, Clinics, and Testing Sites	Hospitals or clinical facility	LabCorp	5,000		elderly, racial and ethnic minorities, healthcare workers, staff for congregate settings, essential workers, first responders, contacts of positive COVID people
H+H Hospitals, Clinics, and Testing Sites	Hospitals or clinical facility	Access DX	20,000		elderly, racial and ethnic minorities, healthcare workers, staff for congregate settings, essential workers, first

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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)
					responders, contacts of positive COVID people
H+H Hospitals, Clinics, and Testing Sites	Hospitals or clinical facility	NY Genome Center	3,000		elderly, racial and ethnic minorities, healthcare workers, staff for congregate settings, essential workers, first responders, contacts of positive COVID people
H+H Hospitals, Clinics, and Testing Sites	Hospitals or clinical facility	Enzo	4,000		elderly, racial and ethnic minorities, healthcare workers, staff for congregate settings, essential workers, first responders, contacts of positive COVID people
CityMD	Hospitals or clinical facility	Quest	6,000		elderly, racial and ethnic minorities, healthcare workers, staff for congregate settings, essential workers, first responders, contacts of positive COVID people
OneMedical	Other	LabCorp	3,000		elderly, racial and ethnic minorities, healthcare workers, staff for congregate settings, essential workers, first responders, contacts of positive COVID people

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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)
Accurate Diagnostics	Other	Accurate/Rutgers Clinical Genomics Lab	4,000		nursing home facilities
H+H Hospitals, Clinics, and Testing Sites	Hospitals or clinical facility	H+H	18,000		elderly, racial and ethnic minorities, healthcare workers, staff for congregate settings, essential workers, first responders, contacts of positive COVID people

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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.

As noted in the Table 1 narrative, NYC is taking a comprehensive and collaborative approach to testing. Capacity has and will continue to be expanded by direct expansion of testing performed at the NYC PHL and at the COVID Express x Quickie Labs run by the NYC PHL out of existing DOHMH clinic sites, increased specimen collection at H+H acute care and primary care clinic sites and at pop-up sites in the community operated by H+H. Specimens collected at these sites will be tested at contracted clinical laboratories. New testing instruments will be procured for the COVID Quickie labs (Cepheid Infinity instruments) to enable high throughput testing with rapid, same day results reported back to the patient, the health department, and directly to CDC through PHLIP. NYC PHL will also add a Roche COBAS instrument, as well as instrumentation to increase serology testing capacity and provide redundancy. In addition, capacity will be added at H+H laboratories in the acute care hospitals through the purchase of Roche COBAS and Cepheid instruments, as well as Abbott instruments to address serology capacity. H+H has contracted with a number of commercial clinical laboratories that will provide testing for specimens collected at H+H sites as well as at “pop-up” testing sites across the city. Given the population density, reliance on mass transit, and the disparity of the impact of this disease on populations, ensuring that testing is available close to those that need it is critical. The existing DOHMH Sexual Health clinics where the COVID Express x Quickie Labs will be located are in communities that experience health inequities and have been hard hit by this disease. The H+H acute care centers and network of primary clinics also serve communities across the city, and pop-up sites will be located strategically to address any gaps. In addition, DOHMH will continue to address testing of populations experiencing homelessness by providing specimen collection on-site and rapid (24 hour) results. DOHMH and H+H are collaborating to address testing in nursing home using contracted laboratories that can test less invasive specimen types like saliva and anterior nares. H+H has partnered with Correctional Health to provide testing for incarcerated populations at Rikers. Testing with swift response at Rikers has thus far successfully avoided any large outbreaks. Health care workers and first responders in NYC have been offered diagnostic and serology testing.

NYC PHL has developed testing capacity using several different platforms and has been successful in avoiding major supply chain issues by being able to nimbly move to another platform. In March, 2020, for example, NYC PHL was able to implement the NYS EUA assay using the BioMerieux EasyMag extraction platform on the same day that the reagents for the Qiagen EZ1 extraction platform, then the only extraction option for the CDC EUA assay, ran out. The transition was seamless. Similarly, H+H has contracts in place with several different commercial clinical labs and is building its own laboratory testing capacity on several platforms. A collaborative team that includes DOHMH and H+H partners with City partners is sourcing collection kit components for the city, with an eye to build redundancy as well as overall volume capacity.

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NYC PHL is in the process of implementing the Diasorin IgG assay on the Liaison instrument. A second instrument has been procured and delivered; this will increase capacity and provide instrument redundancy. NYC PHL will procure instrumentation and implement the Ortho Vitros assay and implement the expected BioRad assay on existing Evolis instruments. Overall, serology capacity will be expandable and redundant, allowing for two-test based testing algorithms to assure true positivity as described by the FDA. In June, DOHMH will launch the first population-based serosurvey to assess the impact of COVID in NYC, with a goal of recruiting 1000 participants aged greater than 18 years for serologic testing. All eligible participants will be offered serology testing; specimens will be collected by a contractor in participant's homes and will be tested at NYC PHL. This will complement the multiple H+H and CDC-backed serosurveys targeting health care workers and other first responders. Seroprevalence in populations experiencing homelessness will be assessed through serosurveys conducted in conjunction with on-going diagnostic testing offered at NYC Department of Homelessness (DHS) shelters throughout the city.

DOHMH and H+H, in part through the Test and Trace program, will conduct ongoing testing in congregate settings, including nursing homes, shelters, and other supportive housing environments. Some of the testing will be performed at the NYC PHL, some will be performed by H+H contracted laboratories.

DOHMH, including NYC PHL will utilize a mix of city hiring as well as hiring through the Fund for Public Health New York to hire staff to support the work. To directly support NYC PHL testing, 15 staff have/will be hired in May, and 128 additional staff will be hired in June. These staff will support expanded testing at the NYC PHL main laboratory as well as testing at the COVID Quickie Labs. The city will hire 783 staff in May and 1269 staff in June to support specimen collection activities at H+H and pop-up sites. To procure instruments, supplies, reagents, collection kits, PPE and all other materials needed to support expanded testing at the NYC PHL and COVID Quickie sites, NYC PHL will continue to leverage existing contracts with vendors and emergency contracting mechanisms as needed, as well as all other available procurement mechanisms to meet needs. Thus far, procurement mechanisms have not been an issue, any shortages have been due only to vendor supply issues and have been mitigated as described above. NYC PHL has been working closely with CDC and HHS partners to ensure that federal allocation of reagents and supplies to NYC PHL is working well. The City has set up working groups that include DOHMH and H+H to source and procure collection kits and other necessary supplies as needed.

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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	783 + 15**	1269 + 128**	**See narrative	Hiring ongoing					0
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)	2 Quidel Sofia 2 Readers	14 Cepheid Infinity-48s; 4 Roche Cobas 6800	90 Roche Liat POC instruments	8 Quidel Sofia 2 Readers					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 swabs needed to meet planned testing levels ⁺⁺	N/A	1,839,000	6,800,000	6,800,000	6,800,000	670,000	670,000	670,000	24,249,000
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels ⁺⁺	N/A	1,839,000	6,800,000	6,800,000	6,800,000	670,000	670,000	670,000	24,249,000

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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)	500/day Cepheid	7000 tests/day Cepheid; 1000 tests/day Roche; 2000 tests/day Hologic Panther; 125 tests/day Quidel; reagents for 170 EasyMag extractions /day	7000 tests/day Cepheid; 11000 tests/day Roche; 2000 tests/day Hologic Panther; 125 tests/day Quidel; reagents for 170 EasyMag extractions /day; 1800 tests/day for Roche Liat	7000 tests/day Cepheid; 11000 tests/day Roche; 2000 tests/day Hologic Panther; 125 tests/day Quidel; reagents for 170 EasyMag extractions /day; 1800 tests/day for Roche Liat	7000 tests/day Cepheid; 11000 tests/day Roche; 2000 tests/day Hologic Panther; 125 tests/day Quidel; reagents for 170 EasyMag extractions /day; 1800 tests/day for Roche Liat	7000 tests/day Cepheid; 11000 tests/day Roche; 2000 tests/day Hologic Panther; 125 tests/day Quidel; reagents for 170 EasyMag extractions /day; 1800 tests/day for Roche Liat	7000 tests/day Cepheid; 11000 tests/day Roche; 2000 tests/day Hologic Panther; 125 tests/day Quidel; reagents for 170 EasyMag extractions /day; 1800 tests/day for Roche Liat	7000 tests/day Cepheid; 11000 tests/day Roche; 2000 tests/day Hologic Panther; 125 tests/day Quidel; reagents for 170 EasyMag extractions /day; 1800 tests/day for Roche Liat	27795
FOR SEROLOGIC TESTING									
Number of additional* equipment and devices to meet planned	11 Abbot Architect; 1 Diasorin Liaison XL		2 Ortho Vitros instruments						0

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BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
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)	40000 tests/day Abbott; 100 tests/day Diasorin	500 tests/day Abbott; 3,000 tests/day Diasorin	500 tests/day Abbott; 3,000 tests/day Diasorin	500 tests/day Abbott; 3,000 tests/day Diasorin, Ortho Vitros, BioRad Platelia	500 tests/day Abbott; 3,000 tests/day Diasorin, Ortho Vitros, BioRad Platelia	500 tests/day Abbott; 3,000 tests/day Diasorin, Ortho Vitros, BioRad Platelia	500 tests/day Abbott; 3,000 tests/day Diasorin, Ortho Vitros, BioRad Platelia	500 tests/day Abbott; 3,000 tests/day Diasorin, Ortho Vitros, BioRad Platelia	

* 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.