

ELC ENHANCING DETECTION: NEW YORK TESTING PLAN

2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	New York
Population Size:	11,000,000

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

The aim of the grant is to increase diagnostic testing capacity to a minimum of 220,000 tests/month. NYS is aiming to test 5% of the population (excluding NYC) with diagnostic assays (550,000 monthly) and we plan to at least maintain, if not increase, that level using multiple approaches:

(a) MAXIMIZE TESTING (a)(1) The New York State Department of Health (NYSDOH) is using a multifaceted approach to maximize testing capacity for COVID-19. The laboratories involved include NYSDOH's Wadsworth Center (WC) as well as hospital, and commercial laboratories (see list in Table 1b). Since WC received authorization from the FDA under an EUA for real-time PCR on February 29, 2020, the WC has validated multiple nucleic acid extraction methods and specimen types. WC has itself performed diagnostic testing on over 68,000 thousand specimens using the NYS FDA-EUA authorized assay and the CDC FDA-EUA authorized semi-automated assay. WC also uses the Cepheid XpertXpress for high priority assays that require a rapid turn-around-time and the NeuMoDx platform for a high throughput sample-to-answer system. Since mid-March, WC has also performed almost 35,000 serology assays for residents across NYS using a high throughput microsphere immunoassay adapted to blood spots. (a)(2) Additionally, in March 2020, the FDA approved NYS to use its regulatory review process to authorize the state's public and private labs to begin manual, semi-automated, and automated testing for COVID-19. (a)(3) NYS has provided potentially high volume laboratories with equipment (7500 Fast PCR platforms, EZ1 extraction systems), supplies (extraction kits, PCR primers and probes, negative and positive controls), and technical assistance. In conjunction with the Office of Emergency Management, NYS has provided 1.3 million collection kits to drive through sites and counties since the beginning of March 2020. To mitigate the shortage of viral transport medium (VTM) the NYSDOH arranged for a local private manufacturing company (Regeneron) to produce 500,000 vials of VTM. (a)(4) NYS has deployed the Abbott rapid assay in nursing homes to test employees but has recently pulled the instruments in view of the recent guidance from the FDA. (a)(5) In order to provide additional capacity, the NYSDOH has initiated a major contract for both molecular diagnostic testing as well as serology testing with a commercial laboratory (Bioreference) to support testing from the drive through sites. (a)(6) In addition, NYS has paired seven commercial labs with specific nursing homes in order to support bi-weekly testing of staff.

(b) INCREASE NUMBER OF TESTING LABORATORIES AND NON-TRADITIONAL SITES: (b)(1) NYS is a CLIA-exempt state and has a lab oversight program, the Clinical Laboratory Evaluation Program (CLEP), that regulates all labs performing testing on samples collected in NYS. CLEP has been very active in working with additional labs that want to on-board COVID-19 testing and permits them when they are appropriate. As of April 19, 2020, there were 217 labs that were approved for COVID-19 testing and as of May 21, 2020, there were 355. (b)(2) In addition, NYS has passed an Emergency Order permitting pharmacists, for the duration of the pandemic, to collect specimens and perform tests using FDA-EUA authorized waived tests. (b)(3) NYSDOH plans to increase capacity of testing laboratories through strong support of two local public health labs in upstate NY (Erie County) and downstate NY (Westchester County). (b)(4) NYSDOH also plans to further establish additional testing locations in non-traditional

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settings such as pharmacies, faith-based organizations, and drive-through and walk-through clinics in rural areas and other underrepresented areas/groups.

(c) STRATEGY FOR SEROLOGY TESTING: (c)(1) The WC has developed three NYS CLEP-approved serology assays: (1) a microsphere-based total antibody immunoassay using the SARS-2-CoV N protein as antigen and blood collected by a venipuncture as the specimen source, (2) an equivalent high throughput IgG assay using blood obtained from a finger stick and collected on filter paper as a blood spot, and (3) a virus neutralization assay using isolate USA-WA1/2020 and Vero E6 cells. Assays #1 and #3 are used to qualify potential plasma donors in collaboration with other NYS institutions. Assay #2 has been used in multiple mobile serosurveys in both specific and random populations around NYS. To date, NYS has surveyed 15,883 patrons of grocery stores, 2,268 first responders, 8,142 health care workers, and 9,946 essential state employees. It is the NYSDOH intention to continue to perform serosurveys using the bloodspot-based assay in both specific and random populations to monitor whether or not seroprevalence in the population is increasing. In addition, a commercial laboratory, under contract with the NYSDOH is providing serology testing to a broader population. All serology results are captured by NYS's reporting system. (c)(2) NYSDOH plans to stand up fixed sites for serology-based testing to assist with health care worker testing, back to work initiatives, and other public health related testing. NYSDOH plans to increase serology testing in community-based settings, vulnerable populations, and other populations such as incarcerated individuals, migrant workers, and those in rural settings without access to testing centers.

(d) COMMUNICATION AND OUTREACH to the broader testing community occurs at multiple levels.

(d)(1) Beginning in the first quarter of this grant, all labs reporting COVID-19 testing results to the NYSDOH will be required to complete a twice weekly electronic survey to monitor equipment, platforms, and capacities to understand throughput and maximize use. (d)(2) Both WC SMEs and the regulatory program SMEs will regularly communicate with the testing laboratories by phone and email to trouble shoot technical problems and resolve regulatory issues. (d)(3) NYSDOH will continue to provide a weekly webinar with health care providers during which a testing update will be provided. (d)(4) Guidance documents will continue to be updated regularly and provided on the NYSDOH website. (d)(5) The NYSDOH will maintain several COVID-19-specific BMLs to which labs can send questions that are forwarded to SMEs for a response.

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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*	220,000	255,000							475,000
Serology	220,000	255,000							475,000
TOTAL	440,000	510,000	0	0	0	0	0	0	

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)
Albany	Drive-thru testing site	Bioref	1,000			General population
Binghamton	Drive-thru testing site	Bioref	1,000			General population
Bronx site 1	Drive-thru testing site	Bioref	1,000			General population
Bronx site 2	Drive-thru testing site	Bioref	1,000			General population
Brooklyn	Drive-thru testing site	Bioref	1,000			General population

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Erie	Drive-thru testing site	Bioref	1,000			General population
Glen Island	Drive-thru testing site	Bioref	1,000			General population
Nassau	Drive-thru testing site	Bioref	1,000			General population
Niagara	Drive-thru testing site	Bioref	1,000			General population
Queens	Drive-thru testing site	Bioref	1,000			General population
Rochester	Drive-thru testing site	Bioref	1,000			General population
Rockland	Drive-thru testing site	Bioref	1,000			General population
Suffolk	Drive-thru testing site	Bioref	1,000			General population
Staten Island	Drive-thru testing site	Bioref	1,000			General population

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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)
Utica/Rome	Drive-thru testing site	Bioref	1,000			General population
Wadsworth Center	Public health lab		1,500	8,000		Nursing homes, adult care homes, prisons, health care workers, congregate living settings, critical outbreak situations, first responders, general population
Access Medical Labs 10D1016867	Commercial or private lab		To be provided (TBP)	TBP		General population
Accu Reference Medical Lab LLC 31D1041265	Commercial or private lab		TBP	TBP		General population
Accurate Diagnostic Labs, Inc 31D1041975	Commercial or private lab		TBP	TBP		General population
ACM Medical Laboratory 33D0654949	Commercial or private lab		TBP	TBP		General population

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Acutis Diagnostics 33D2087537	Commercial or private lab		TBP	TBP		General population
AdvantageCare Physicians PC - 33D2181448, 33D1068941, 33D2166725, 33D1068933, 33D0724513, 33D0860104, 33D0706383, 33D0160105, 33D2166705, 33D0858319, 33D0983074, 33D2131058	Hospitals or clinical facility		TBP	TBP		General population
Aegis Sciences Corporation 44D2062333	Commercial or private lab		TBP	TBP		General population

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All Med Rehabilitaion 33D2005692	Hospitals or clinical facility		TBP	TBP		General population
Arnot Ogden Medical Center 33D0174823	Hospitals or clinical facility		TBP	TBP		General population
ARUP LABORATORIES 46D0523979	Commercial or private lab		TBP	TBP		General population
AUBURN 33D0668978	Hospitals or clinical facility		TBP	TBP		General population
Bellevue Hospital Center 33D0653357	Hospitals or clinical facility		TBP	TBP		General population
BIOCOLLECTIONS WORLDWIDE, INC. 10D1042897	Commercial or private lab		TBP	TBP		General population
BIOREFERENCE LABORATORIES INC 31D0652945	Commercial or private lab		TBP	TBP		General population

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Boston Heart Diagnostics 22D2100622	Commercial or private lab		TBP	TBP		General population
Bradley A Connor MD PLLC 33D0865305	Hospitals or clinical facility		TBP	TBP		General population
Bronx Lebanon Hospital Center 33D0671605	Hospitals or clinical facility		TBP	TBP		Veterans
BRONX VAMC 33D0987193	Hospitals or clinical facility		TBP	TBP		General population
BROOKDALE 33D0145613	Hospitals or clinical facility		TBP	TBP		General population
Canton-Potsdam 33D0167788	Commercial or private lab		TBP	TBP		General population
CapialCare Medical Group 33D0682770	Hospitals or clinical facility		TBP	TBP		General population

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CareMount Medical 33D1103497	Hospitals or clinical facility		TBP	TBP		General population
Catholic Health - Mercy 33D0665319	Hospitals or clinical facility		TBP	TBP		General population
Catholic Health - Sisters 33D0009988	Hospitals or clinical facility		TBP	TBP		General population
Catholic Health Regional Laboratory 33D1103496	Hospitals or clinical facility		TBP	TBP		General population
Cayuga Medical Center 33D0010445	Hospitals or clinical facility		TBP	TBP		General population
CENTREX 33D0167134	Commercial or private lab		TBP	TBP		General population
Champlain Valley Physicians Hospital 33D0654503	Hospitals or clinical facility		TBP	TBP		General population

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Columbia Memorial 33D0163422	Hospitals or clinical facility		TBP	TBP		General population
Columbia Memorial Hospital 33D0163422	Hospitals or clinical facility		TBP	TBP		General population
Coney Island Hosp 33D0725347	Hospitals or clinical facility		TBP	TBP		General population
Crystal Run 33D2094497	Hospitals or clinical facility		TBP	TBP		General population
Danbury Hospital 07D0101031	Hospitals or clinical facility		TBP	TBP		General population
Department of Pathology and Laboratory Medicine at Albany Medical Center 33D0706893	Hospitals or clinical facility		TBP	TBP		General population

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Edward M. Condon Medical P.C. 33D1087089	Hospitals or clinical facility		TBP	TBP		General population
Ellis Hospital 33D0162651	Hospitals or clinical facility		TBP	TBP		General population
Elmhurst Hospital Center 33D0008001	Hospitals or clinical facility		TBP	TBP		General population
EMES Professional Associates Inc dba QDx Pathology Services 31D2026917	Commercial or private lab		TBP	TBP		General population
EMPIRECITY LABORATORIES 33D1057336	Commercial or private lab		TBP	TBP		General population
ENZO 33D0159701	Commercial or private lab		TBP	TBP		General population

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Erie County Medical Ctr Clinical Labs 33D0009994	Hospitals or clinical facility		TBP	TBP		General population
Erie County PHL 33D0654777	Public health lab		TBP	TBP		General population
Exact Sciences Laboratories LLC 52D2072838	Commercial or private lab		TBP	TBP		General population
FCMG Central Laboratories 33D0165349	Commercial or private lab		TBP	TBP		General population
Flushing Medical Center 33D0149282	Hospitals or clinical facility		TBP	TBP		General population
GENEVA GENERAL HOSPITAL 33D0665310	Hospitals or clinical facility		TBP	TBP		General population
Glens Falls Hospital 33D0330191	Hospitals or clinical facility		TBP	TBP		General population

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Good Samaritan 33D0159925	Hospitals or clinical facility		TBP	TBP		General population
Guthrie Cortland Medical Center 33D0165476	Hospitals or clinical facility		TBP	TBP		General population
GUTHRIE MEDICAL GROUP LABORATORY 39D0193451	Hospitals or clinical facility		TBP	TBP		General population
Harlem Hospital Center 33D0677275	Hospitals or clinical facility		TBP	TBP		General population
HistoPathology Services LLC 33D1102785	Commercial or private lab		TBP	TBP		General population
HOSPITAL FOR SPECIAL SURGERY 33D0712044	Hospitals or clinical facility		TBP	TBP		General population
Hudson Valley Hospital Center 33D0138785	Hospitals or clinical facility		TBP	TBP		General population

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Jacobi Medical Center 33D0668554	Hospitals or clinical facility		TBP	TBP		General population
Jamaica Hospital 33D0152608	Hospitals or clinical facility		TBP	TBP		General population
John T Mather 33D0158831	Hospitals or clinical facility		TBP	TBP		General population
Kaleida Health 33D0669255	Hospitals or clinical facility		TBP	TBP		General population
KH DEGRAFF 33D0654753	Hospitals or clinical facility		TBP	TBP		General population
Kings County Hospital Center 33D0676479	Hospitals or clinical facility		TBP	TBP		General population
Kingsbrook Jewish Medical Center 33D0144588	Hospitals or clinical facility		TBP	TBP		General population

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Lab Alliance of Central NY 33D0954150	Commercial or private lab		TBP	TBP		General population
LABCORP 34D0655059	Commercial or private lab		TBP	TBP		General population
Lawrence Hospital 33D0007033	Hospitals or clinical facility		TBP	TBP		General population
Lenco 33D1012663	Commercial or private lab		TBP	TBP		General population
Lincoln Diagnostic Lab 31D2118440	Commercial or private lab		TBP	TBP		General population
Lincoln Medical and Mental Health Center 33D0135629	Hospitals or clinical facility		TBP	TBP		General population
Long Island FQHC Inc 33D0934171	Hospitals or clinical facility		TBP	TBP		General population

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Lourdes Hospital 33D0168541	Hospitals or clinical facility		TBP	TBP		General population
Maimonides Medical Center 33D0146527	Hospitals or clinical facility		TBP	TBP		General population
Mayo Clinic DLMP 24D0404292	Hospitals or clinical facility		TBP	TBP		General population
Medical Diagnostic Laboratories 31D0938156	Commercial or private lab		TBP	TBP		General population
Memorial Sloan Kettering Cancer Center 33D0670454	Hospitals or clinical facility		TBP	TBP		General population
Mercy Medical Center 33D0153094	Hospitals or clinical facility		TBP	TBP		General population
Metropolitan Hospital Center 33D0717970	Commercial or private lab		TBP	TBP		General population

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MidHudson Regional Hospital 33D0666319	Hospitals or clinical facility		TBP	TBP		General population
Mid-Hudson Valley Division of Westchester Medical Center Laboratory 33D0666319	Hospitals or clinical facility		TBP	TBP		General population
Montefiore Medical Center - 33D0669651, 33D0712594, 33D0136308, 33D0136383, 33D0653713	Hospitals or clinical facility		TBP	TBP		General population
Montefiore Nyack Hospital Affiliated Lab 33D0142068	Hospitals or clinical facility		TBP	TBP		General population
Mount Sinai Hospital 33D0653419	Hospitals or clinical facility		TBP	TBP		General population

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Nassau University Medical Center 33D0153869	Hospitals or clinical facility		TBP	TBP		General population
National Guard - Schenectady 33D2183327	Drive-thru testing site		TBP	TBP		
New Milford Hospital 07D0101031	Hospitals or clinical facility		TBP	TBP		General population
New York University Langone Medical Center 33D0653358	Hospitals or clinical facility		TBP	TBP		General population
New York-Presbyterian Hospital 33D0664858, 33D0664187, 33D0133991, 33D0653378, 33D0872522	Hospitals or clinical facility		TBP	TBP		General population
North Shore Hematology -	Hospitals or clinical facility		TBP	TBP		General population

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Oncology Associates PC						
Northern Dutchess Hospital 33D0158740	Hospitals or clinical facility		TBP	TBP		General population
Northwell - 33D0128186, 33D0008369, 33D0654099, 33D0665276, 33D0668414, 33D0653806, 33D0653799, 33D0160326, 33D0675969, 33D0653792	Hospitals or clinical facility		TBP	TBP		General population
Northwern Westchester 33D0653627	Hospitals or clinical facility		TBP	TBP		General population

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Nuvance Health West Laboratories 33D1027395	Commercial or private lab		TBP	TBP		General population
NYCDOHMH Public Health Lab 33D0679872	Public health lab		TBP	TBP		General population
P4 Clinical, LLC (Manhattan Physicians)	Commercial or private lab		TBP	TBP		General population
Phelps Memorial Hospital 31D0106549	Hospitals or clinical facility		TBP	TBP		General population
Putnam Hospital Center 33D1027395	Hospitals or clinical facility		TBP	TBP		General population
Quality Laboratory Services 33D1018138	Commercial or private lab		TBP	TBP		General population
Queens Hospital Center 33D0682879	Hospitals or clinical facility		TBP	TBP		General population

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Quest Diagnostics - 31D0696246, 49D0221801, 39D0656976, 11D0255931, 39D0183896, 17D0648226, 22D0076229, 39D0656976, 05D0643352, 10D0291120, 31D0696246, 05D0642827, 14D0417052	Commercial or private lab		TBP	TBP		General population
RDX BioScience 31D2009100	Commercial or private lab		TBP	TBP		General population
Refuah Health Center 33D0876672	Hospitals or clinical facility		TBP	TBP		General population

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Richmond University Medical Center 33D0006466	Hospitals or clinical facility		TBP	TBP		General population
ROCHESTER GEN HOSP 33D0173444	Hospitals or clinical facility		TBP	TBP		General population
Rockefeller University Clinical Genomics Laboratory 33D2127777	Hospitals or clinical facility		TBP	TBP		General population
Roswell Park Cancer Institute Div. Of Pathology 33D0171366	Hospitals or clinical facility		TBP	TBP		General population
Saint Catherine of Siena Medical Center 33D0159343	Hospitals or clinical facility		TBP	TBP		General population
Saint Charles Hospital 33D0158845	Hospitals or clinical facility		TBP	TBP		General population

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Saint Francis Hospital 33D0155021	Hospitals or clinical facility		TBP	TBP		General population
Saint Joseph Hospital 33D0156376	Hospitals or clinical facility		TBP	TBP		General population
Samaritan Hospital Laboratory - 33D0161727, 33D0167537	Hospitals or clinical facility		TBP	TBP		General population
Saratoga Hospital 33D0164868	Hospitals or clinical facility		TBP	TBP		General population
Seneca Nations Health System 33DSENECA1	Hospitals or clinical facility		TBP	TBP		General population
Sharon Hospital 07D0644532	Hospitals or clinical facility		TBP	TBP		General population

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Sherman Abrams Laboratory Inc 33D0146545	Commercial or private lab		TBP	TBP		General population
SHH LABORATORY 33D0160804	Commercial or private lab		TBP	TBP		General population
SMA Medical Laboratories 39D0987158	Commercial or private lab		TBP	TBP		General population
South Nassau Communities Hospital 33D0154862	Hospitals or clinical facility		TBP	TBP		General population
St Marys Hospital 33D0160936	Hospitals or clinical facility		TBP	TBP		General population
St. Barnabas Health System 33D0135938	Hospitals or clinical facility		TBP	TBP		General population
St. John's Episcopal Hospital 33D0654102	Hospitals or clinical facility		TBP	TBP		General population

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St. Luke's Hospital - 33D0676871, 33D0166941	Hospitals or clinical facility		TBP	TBP		General population
St. Peters Hospital Laboratory 33D0162320	Hospitals or clinical facility		TBP	TBP		General population
Staten Island Univ Hospital - 33D0134977, 33D2092932, 33D0725182	Hospitals or clinical facility		TBP	TBP		General population
Stony Brook University Hospital 33D0654233	Hospitals or clinical facility		TBP	TBP		General population
SUNRISE MEDICAL LABORATORIES 33D0654120	Commercial or private lab		TBP	TBP		General population
SUNY Upstate Medical University Clinical Pathology Laboratory 33D0654590	Hospitals or clinical facility		TBP	TBP		General population

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The Brooklyn Hospital Center 33D0667136	Hospitals or clinical facility		TBP	TBP		General population
THE MARY IMOGENE BASSETT HOSPITAL COOPERSTOWN LABORATORY 33D0654609	Hospitals or clinical facility		TBP	TBP		General population
Total Renal Labs Inc dba DaVita Laboratory Service 10D0645475	Commercial or private lab		TBP	TBP		General population
University Hospital of Brooklyn 33D0707787	Hospitals or clinical facility		TBP	TBP		General population
UPMC WCA Hospital 33D0174000	Hospitals or clinical facility		TBP	TBP		General population
UR Medicine Labs-Central Laboratory 33D1068640	Hospitals or clinical facility		TBP	TBP		General population

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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)
UVMMC 47D0660960	Hospitals or clinical facility		TBP	TBP		General population
VA Health Care System - 33DVAHUDSN, 33D0987132, 33D0987189	Hospitals or clinical facility		TBP	TBP		Veterans
VA Medical Centers - 33VAALBANY, 33DVABATH, 33D0987196	Hospitals or clinical facility		TBP	TBP		Veterans
Vassar Brothers Medical Center 33D0654442	Hospitals or clinical facility		TBP	TBP		General population
Viracor-Eurofins Laboratories 26D0983643	Commercial or private lab		TBP	TBP		General population
WESTCHESTER MEDICAL CENTER 33D0721132	Hospitals or clinical facility		TBP	TBP		General population

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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)
White Plains Hospital 33D0006959	Hospitals or clinical facility		TBP	TBP		General population
Wilson Memorial Hospital 33D0654691	Hospitals or clinical facility		TBP	TBP		General population
Woodhull Medical Center 33D0144811	Hospitals or clinical facility		TBP	TBP		General population
Wyckoff Heights Medical Center 33D0726426	Hospitals or clinical facility		TBP	TBP		General population
XERON CLINICAL LABS 33D0931561	Commercial or private lab		TBP	TBP		General population
Yale New Haven 07D0098656	Hospitals or clinical facility		TBP	TBP		General population

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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.

The NYSDOH will accomplish the goal of providing testing for 5% of the upstate population of NYS on a monthly basis. The goal, as NYS gradually re-opens will be achieved by (1) maintaining current testing strategies, (2) intensifying contact tracing, comprehensively monitoring and testing contacts of infected persons, and (3) ensuring that the most vulnerable populations are tested. The purpose is to ensure that the R0, the measure of the number of people an infected person will transmit the virus to, is maintained at less than one. NYSDOH will accomplish this in the following multicomponent manner:

(a)(1) MAXIMIZE CAPACITY AND ACCESS AND OPTIMIZE TESTING: In addition to utilizing multiple platforms, the WC has developed and continues to explore alternate methods for sample collection to streamline collection and enhance convenience and accessibility. WC developed a new, less intrusive test for COVID-19 that is completed through a saliva sample or alternately, a self-administered short nasal swab in the presence of a health care professional. Additionally, health care professionals can self-administer the test without another health care professional present. (a)(2) INCREASE TESTING SITES: NYS is a CLIA-exempt state and has a lab oversight program, the Clinical Laboratory Evaluation Program (CLEP), that regulates all labs performing testing on samples collected in NYS. CLEP has been very active in working with additional labs that want to on-board COVID-19 testing and permits them when they are appropriate. As of April 19, 2020, there were 217 labs that were approved for COVID-19 testing and as of May 21, 2020, there were 355. In addition, NYS has passed an Emergency Order permitting pharmacists, for the duration of the pandemic, to collect specimens and perform tests using FDA-EUA authorized waived tests. In addition, support will be provided to two County Laboratories in impacted areas of the state, to enhance their capacity for testing. (a)(3) CONTACT TRACING: NYS has established a contact tracing work force of 3,000 individuals using both local health department and contract staff and is working closely with the 57 counties to ensure that all contacts of PCR-confirmed infected persons are contacted, placed in quarantine and monitored for the development of symptoms. (a)(4): DRIVE THROUGH: NYS maintains fifteen regional drive-throughs as testing sites. Drive-through sampling sites are a critical part of the program to test for COVID-19. These facilities reduce density and the potential for spread by keeping people who are sick or at risk of having contracted coronavirus out of healthcare facilities where they could infect other people.

(b) TESTING FOR VULNERABLE AND AT RISK POPULATIONS. The Governor has required that all residents of NYS nursing homes be tested and that nursing home employees also be tested twice per week. NYS has been divided into two regions: upstate and downstate. Downstate testing is being performed under contract with a commercial laboratory and testing in nursing homes in upstate counties is provided by WC. To support bi-weekly testing of staff, the state has paired seven commercial labs with specific nursing homes. Additionally, WC is testing samples from non-traditional submitters including correctional facilities and adult and group homes.

(c) OVERCOMING BARRIERS: (c)(1) TRANSPORT of specimens to the WC has been a crucial issue because of the importance of maintaining a short turnaround time. NYSDOH has established a highly coordinated Critical Specimen Transport System to support this logistical function. The involvement of State Police

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has been crucial in its success. (c)(2) Laboratory Information Management System (LIMS): At the WC, this experience has identified gaps in our current accessioning and laboratory information management system (LIMS) that limit efficiency. The pandemic has exposed the need for a patient portal to allow rapid access of test results to the public and avoid the overwhelming burden of requests for test results and reports that has occurred to date. The WC plans to enhance our current system to allow for easier upload of test requests and reporting of laboratory results. WC also needs to establish automatic processes for the upload of laboratory data into our LIMS from the numerous new testing platforms that we have obtained to be able to manage the test data. (c)(3) MONITORING STATUS: In the first quarter of the grant, all labs reporting COVID-19 testing results to the NYSDOH will be required to complete a twice weekly electronic survey to monitor equipment, platforms, and capacities to understand throughput and maximize use. (c)(4) COMMUNICATION: Both WC SMEs and the regulatory program SMEs will regularly communicate with the testing laboratories by phone and email to trouble shoot technical problems and resolve regulatory issues.

(d) STRATEGY FOR SEROLOGY TESTING: (d)(1) WC has developed three NYS CLEP-approved serology assays: (1) a microsphere-based total antibody immunoassay using the SARS-2-CoV N protein as antigen and blood collected by a venipuncture as the specimen source, (2) an equivalent high throughput IgG assay using blood obtained from a finger stick and collected on filter paper as a blood spot, and (3) a virus neutralization assay using isolate USA-WA1/2020 and Vero E6 cells. Assays #1 and #3 are used to qualify potential plasma donors in collaboration with other NYS institutions. Assay #2 has been used in multiple serosurveys in both specific and random populations around NYS. To date, NYS has surveyed 15,883 patrons of grocery stores, 2,268 first responders, 8,142 health care workers, and 9,946 essential state employees. It is the NYSDOH intention to continue to perform serosurveys using the bloodspot-based assay in both specific and random populations to monitor whether or not seroprevalence in the population is increasing. In addition, a commercial laboratory, under contract with the NYSDOH is providing serology testing to a broader population. All serology results are captured by NYS's reporting system.

(e) PLAN FOR RESOURCE UTILIZATION: (e)(1) In the first quarter of the grant, all labs reporting COVID-19 testing results to the NYSDOH will be required to complete a twice weekly electronic survey to monitor equipment, platforms, and capacities to understand throughput and maximize use. This will allow the NYSDOH to re-direct testing if one particular lab is overwhelmed and to re-direct supplies to support a critical testing need including high risk outbreaks and surveillance in vulnerable populations. (e)(2) The NYSDOH will build on existing reporting systems and activities used for sentinel surveillance of the flu to expand and perform sentinel surveillance for COVID-19.

(f)(1) NYSDOH PLAN TO EXPEDITE PROCESSES: (f)(1) The funds will be managed through the NYSDOH's sister organization, Health Research, Inc.(HRI). HRI is an independent, private, not-for-profit corporation qualified under sec. 501(c)(3) of the IRS Code. It is legally recognized by NYS as a "Research Institute" and a "State Affiliated Corporation" in State Finance Law (Section 53-a, State Finance Law). HRI's primary purpose is to provide a vehicle through which scientists and public health professionals can successfully compete for extramural grants to support public health programs. Clients include NYSDOH, Roswell Park Cancer Institute, and related outside organizations, both public and private. The flexibility, speed, and expertise provided by HRI are essential in attracting and securing this external grant funding in a highly competitive environment. HRI is an active partner with the ability to quickly recruit and hire qualified candidates and to execute contracts to assist its clients to carry out public health initiatives.

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(f)(2) In addition, the NYSDOH will working closely with the Office of Emergency Management within the Department of Homeland Security and Emergency Services to purchase and transport supplies, reagents, test kits, and collection materials.

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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	0	17							17
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)	TBD	TBD							0
Volume of additional swabs needed to meet planned testing levels ⁺⁺	60,000	60,000							120,000
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels ⁺⁺	60,000 vials	60,000 vials							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)	2,000 tests per day, Platform TBD	2,000 tests per day, Platform TBD							
FOR SEROLOGIC TESTING									

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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	Two OrthoClinical platforms	X							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)	2,000 blood spots, antibodies, Luminex beads	2,000 blood spots, antibodies, Luminex beads							

* 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.