



U.S. Department of Health and Human Services

REPORT TO CONGRESS

COVID-19 Strategic Testing Plan

May 24, 2020

Table of Contents

Executive Summary	3
List of Acronyms	4
Introduction	6
Testing Goals and State Plans	8
Federal Government Support to States	19
Increasing Testing Capacity	27
Resources for Testing	36
Mechanisms for Responding to Future Pandemics	40
Conclusion	43
Appendix A	44
Appendix B	52
Appendix C	53
Appendix D	69

Executive Summary

This report to Congress is in response to the Paycheck Protection Program and Health Care Enhancement Act, P.L. 116-139. The Act states:

Provided further, That not later than 30 days after the date of the enactment of this Act, the Secretary, in coordination with other departments and agencies, as appropriate, shall report to the Committees on Appropriations of the House and Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate on a COVID-19 strategic testing plan: Provided further, That such plan shall assist States, localities, territories, tribes, tribal organizations, and urban Indian health organizations, in understanding COVID-19 testing for both active infection and prior exposure, including hospital-based testing, high-complexity laboratory testing, point-of-care testing, mobile-testing units, testing for employers and other settings, and other tests as necessary: Provided further, That such plan shall include estimates of testing production that account for new and emerging technologies, as well as guidelines for testing: Provided further, That such plan shall address how the Secretary will increase domestic testing capacity, including testing supplies; and address disparities in all communities: Provided further, That such plan shall outline Federal resources that are available to support the testing plans of each State, locality, territory, tribe, tribal organization, and urban Indian health organization: Provided further, That such plan shall be updated every 90 days until funds are expended: Provided further, That such amount is designated by the Congress as being for an emergency requirement pursuant to section 251(b)(2)(A)(i) of the Balanced Budget and Emergency Deficit Control Act of 1985.

This report details the COVID-19 strategic testing plan for the U.S. Department of Health and Human Services, as executed by the Secretary among the Department's agencies and offices, and in coordination with other departments and agencies, as appropriate.

This report is the first report pursuant to this section of the Paycheck Protection Program and Health Care Enhancement Act and will be updated every 90 days until funds are expended, as required by Congress.

List of Acronyms

ACLA	American Clinical Laboratory Association
ASPR	Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
CBTS	Community based testing sites
CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare & Medicaid Services
COVID-19	Coronavirus Disease 2019
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
DARPA	Defense Advanced Research Projects Agency
DoE	Department of Energy
DNA	Deoxyribonucleic acid
DoD	Department of Defense
DPA	Defense Production Act
EHR	Electronic health record
ELR	Electronic laboratory-based reporting
EUA	Emergency use authorization
FDA	Food & Drug Administration
FEMA	Federal Emergency Management Agency
HHS	Department of Health and Human Services
HIV	Human immunodeficiency virus
HRSA	Health Resources & Services Administration
IHS	Indian Health Service
LIMS	Laboratory information management systems
MCM	Medical countermeasure
NCI	National Cancer Institute
NGS	Next generation sequencing

**U.S. Department of Health and Human Services
Report to Congress: COVID-19 Strategic Testing Plan**

NIAID	National Institute of Allergy and Infectious Disease
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NIH	National Institutes of Health
OASH	Office of the Assistant Secretary for Health
OIG	Office of the Inspector General
OSTP	Office of Science and Technology Policy
PCR	Polymerase chain reaction
PHL	Public Health Laboratories
PHSSEF	Public Health and Social Services Emergency Fund
POC	Point-of-care
PPE	Personal protective equipment
RADx	Rapid Acceleration of Diagnostics
RNA	Ribonucleic acid
RT-PCR	Reverse transcription polymerase chain reaction
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SVI	Social Vulnerability Index
VTM	Viral transport medium
WHO	World Health Organization

Introduction

Testing is a critical component of the public health response to SARS-CoV-2 (the virus that causes COVID-19). It enables clinical decision making, informs resource allocation and disease prevalence monitoring, and is necessary to minimize economic and community disruption through targeted infection prevention and control measures. Testing a majority of the U.S. population, recurrently, is neither feasible nor necessary to assure safe return to work, school, and other activities. In fact, a targeted strategy based on diagnosis, contact tracing, and smart surveillance is the optimum approach – especially when combined with syndromic surveillance and hygiene.

On April 27, 2020, the President released *Opening Up America Again Guidelines: Testing Overview*ⁱ and *Opening Up America Again Guidelines: Testing Blueprint*ⁱⁱ. The *Opening Up America Again Guidelines: Testing Overview* and *Testing Blueprint* are designed to facilitate State development and implementation of testing plans and rapid response programs.

The *Opening Up America Again Guidelines: Testing Overview* lays out an 8-part plan in three stages:

Stage 1: Launch

1. Build the foundation for diagnostic testing
2. Mobilize the private sector to develop tests
3. Issue emergency use authorizations (EUAs) for tests
4. Galvanize commercial and research laboratories and professional associations to ramp up testing capacity
5. Facilitate State efforts to access and utilize all available testing capacity

Stage 2: Scale

6. Identify and expand public and private-sector testing infrastructure and capacity
7. Strengthen the supply chain for testing

Stage 3: Support Opening Up Again

8. Coordinate with governors to support testing plans and rapid response programs

This report supports the implementation of the 8-part plan by providing additional guidance and information about diagnostic technologies, platforms and inventory that States, territories and tribes can utilize to develop flexible, adaptable, and robust plans.

The *Testing Blueprint* supports the opening of America and outlines the roles and responsibilities of the Federal, State, local, and tribal governments, private sector, and professional associations.

**U.S. Department of Health and Human Services
Report to Congress: COVID-19 Strategic Testing Plan**

The *Testing Blueprint* provides guidance and outlines core elements for States as they develop their testing strategies. It outlines a partnership among Federal, State, local, and tribal governments that will result in our ability to meet testing goals now and in the future. The role of the Federal government is to enable innovation, help scale supplies, and provide strategic guidance. States, territories, and tribes are responsible for formulating and implementing testing plans; and the private sector will continue to develop and produce technologies, supplies, and services to meet the needs of the States. The Paycheck Protection Program and Health Care Enhancement Act (Public Law 116-139), signed on April 24, 2020, provides a minimum of \$11 billion to State, local, territory, tribe, or tribal (SLTT) organizations to develop, purchase, administer, process, and analyze COVID-19 tests, scale-up laboratory capacity, trace contacts, and support employer testing. States, territories, and tribes will utilize the substantial federal resources provided to them to meet their testing goals.

When developing testing strategies, States, territories and tribes should consider testing technologies, use cases for these technologies, and available inventory. Appendix A highlights current diagnostic assays and potential use cases. In addition, strategies should be considered living documents and adapted as needed to account for the latest information about disease transmissibility and immunity. Strategies should be flexible enough to incorporate new diagnostic technologies where appropriate and fit-for-purpose. At a minimum, a State's testing plan should include the following:

- How the state, territory, and tribal area will meet testing goals/targets;
- Where testing will be performed (commercial; academic; medical centers; public health labs, retail sites);
- Description of the SARS-CoV-2 testing capacity and ecosystem in the State;
- Capabilities to overcome barriers to efficient testing;
- Mechanisms to leverage the entire testing ecosystem;
- Use of new and emerging technologies, as they develop;
- A reporting structure to inform clinical care and public health decision-making;
- Mechanisms to rapidly identify any newly emergent cases or clusters of COVID-19 among symptomatic and asymptomatic individuals;
- Protocols to facilitate contact tracing and isolation strategies for newly diagnosed cases; and
- A process to ensure that underserved and high-risk populations receive adequate testing services, through the most effective means.

As the Federal government works to mitigate the spread of the virus, save lives, and safely reopen America, the primary purpose of this report is to discuss the country's immediate and near-term testing needs and how these are being addressed. Among other goals, as described in this report, the Federal government will implement testing for at-need communities.

The first update to this report will include additional information on guidance, goals, projects, and programs that will advance the testing ecosystem in the U.S. These innovative programs could include activities related to:

- Robust, secure data collection and utilization systems;
- Domestic production and supply chain management capabilities for testing supplies and reagents; and
- Public-private partnerships that will result in enhanced testing capacity in specific communities across the U.S.

In addition, it will be critical for all programs to evaluate and subsequently implement the most effective methods and infrastructure for reaching underserved and high-risk populations. These items are discussed briefly in the last section of the report, "Mechanisms for Responding to Future Pandemics," and will be further detailed in HHS' first update to this report to Congress on testing plans.

Testing Goals and State Plans

Testing for active infection with SARS-CoV-2 first requires collecting a nasal, nasopharyngeal, or oropharyngeal swab from a patient. The swab is then placed into a test tube with transport media and sent to a lab for testing; or tested directly at the point-of-care (POC) (e.g. physician's office, long term care facility) with a POC testing device. If the sample is sent to the laboratory for testing, a two-step testing process is performed. The first step is the extraction of the nucleic acid/genomic material from the virus. The second step is a reverse-transcriptase polymerase chain reaction (RT-PCR) which amplifies the target nucleic acid from the virus present in the sample. Both steps require reagents that typically come in the form of a kit (extraction kit or RT-PCR kit). See Appendix B for a more detailed description of this process.

Diagnostic assays to test for SARS-CoV-2 can be categorized as either: (1) those that test for active infection or (2) those that test for prior infection. Currently authorized tests used to identify active infections detect either viral nucleic acid (genetic material) or antigen (protein). Serologic tests, which indicate prior infection, detect antibodies. Additional information about these types of tests can be found in Appendix A. Tests for active infection (e.g. nucleic acid detection and antigen detection tests) can be performed in either a laboratory or at point-of-care

(POC), e.g. at a physician's office. At this time, serological testing (e.g. prior infection tests) are authorized only in a laboratory setting.

Testing for the presence of active infection provides critical information that can be used to manage the COVID-19 response. There are three primary purposes for active infection testing:

- **Diagnostic Testing** is used to confirm or support a clinical diagnosis of viral infection in symptomatic individuals and inform treatment and implement preventive measures to contain further spread.
- **Testing for Contact Tracing** is a process to trace, test, and monitor persons that may have been in contact with infected individuals. This type of testing supports the identification and rapid isolation of new cases or those with presence of virus and no symptoms and helps to prevent further spread.
- **Surveillance Testing** is used to limit the spread of disease and enable public health authorities to assess and manage the risks associated with COVID-19, including testing asymptomatic individuals. Objectives of surveillance include enabling rapid detection, isolation, testing, and management of suspected cases; guiding the implementation of control measures; detecting and containing outbreaks among vulnerable populations; and monitoring long-term epidemiological trends.ⁱⁱⁱ

In addition to testing for an active infection, testing for a previous infection is performed using serologic tests. Serology (antibody) testing complements diagnostic testing (testing for active infection) by evaluating the prevalence of individuals in a community and across the U.S. who were previously infected by the virus. At this time, a positive antibody test does not indicate with certainty that an individual is immune to reinfection. Additional studies are ongoing to determine if the presence of antibodies to the virus, and at what levels, correlates with protective immunity.

Diagnostic testing, contact tracing, and surveillance testing are the most critical components of our immediate testing strategy. The specific number of tests that are required in each State, and in each geographical region within each State, depends on numerous factors, including but not limited to:

- *The percent positives in a State, territory, or tribe.* The World Health Organization (WHO) set an objective that the percent of tests being positive should be 10 percent or lower, demonstrating that 10 times as many people are being tested as have the disease. This indicates enough testing exists to ensure broad coverage of the population. The amount of testing needed in a community is situational (based on geography, transmission, vulnerable populations, etc.), but in general, achieving this benchmark begins to ensure rapid diagnosis of symptomatic and asymptomatic individuals.

- *The characteristics of the population.* Areas with large numbers of individuals at high risk of contracting or transmitting the virus, or who may be highly vulnerable for having poor outcomes, will require increased surveillance testing.
- *The degree of mitigation employed in that community.* Mitigation strategies such as social distancing help control the spread of disease. In areas where mitigation strategies are strictly implemented, there will be less contact tracing needed and less concern of spread to vulnerable populations. When mitigation measures are relaxed, the number of social contacts will increase as does the potential risk of infection – making widespread testing and early warning more critical than during full community mitigation.

In addition to the factors listed above, there are many additional considerations such as the availability of resources, presence of concurrent, seasonal respiratory infections (such as influenza), prevalence of potentiating risk factors among communities, such as asthma or diabetes, that must be taken into account when developing and or adapting a testing strategy. Therefore, the testing strategy, as well as the specific quantitative goals for testing, should be continually informed by epidemiological data as well as our evolving understanding of the ecology of the virus.

The National Approach to Testing for SARS-CoV-2

From the onset of the pandemic, and continuing into the future, the Federal government will work with States, territories, localities, and tribes to support the development and availability of as many fully enabled tests as possible. This work will continue as determined by epidemiological factors (e.g. decreased number of cases), transmission, population immunity, and/or through availability of safe and effective vaccines that broad scale testing is no longer needed.

In early March, only a few thousand tests for COVID-19 were performed each day. In mid-May, that number is approximately 300,000 per day, and growing steadily at 25%-30% per week. With expanded and sustainable supply chains, novel “front ends” (e.g. retail stores, community based testing sites) for testing, and States becoming empowered with enhanced knowledge and funding, we will maintain our testing capacity and continue to grow these numbers significantly over the next several months.

The Federal government is supporting and encouraging States, territories, and tribes to build a multi-layered approach that incorporates and fully leverages all components of the testing ecosystem. State strategies should evaluate and utilize testing across their ecosystem (in commercial, academic, medical center, and public health laboratories). In addition, States and jurisdictions should apply the different types of SARS-CoV-2 testing that are appropriate for different environments, fit for purpose, and currently available. The Centers for Disease Control and Prevention (CDC) guidance on prioritizing applications of the various types of tests (e.g. nucleic acid, antigen, and antibody detection) and testing materials will be crucial for how States plan, adapt, and implement robust testing strategies.^{iv,v}

Testing Ecosystem:

- **Commercial Reference Laboratories:** American Clinical Laboratory Association (ACLA)-member laboratories (for example Quest Diagnostics, LabCorp, Mayo Clinic Laboratories, ARUP, BioReference Laboratories, and others) are regional or national in scale. These laboratories have hundreds to thousands of patient service centers (sample collection sites) that are located throughout the nation. In fact, more than 93% of the U.S. population lives within 10 miles of a patient service center. At the time of this report, ACLA-member laboratories have performed more than 6.5 million tests for SARS-CoV-2, approximately half of the total performed in the nation. Moving forward, ACLA-member laboratories anticipate having the capacity to perform over five million tests per month, and perhaps double that number depending on anticipated demand and expansion. These labs utilize high throughput, highly complex diagnostic platforms. Results are typically available within 24-48 hours of sample collection.
- **Hospital and Academic Laboratories:** The extensive network of hospitals, academic medical centers, and university clinical laboratories are a critical component of the U.S. testing ecosystem. Many of the laboratories are just beginning to ramp up testing for SARS-CoV-2 and are not yet fully utilizing the maximum capacity for their instruments. In order for the nation to meet our testing goals for SARS-CoV-2, we must ensure full utilization of this extensive network. Clinical laboratories of this type routinely utilize moderate to high throughput platforms. For example, a majority of the Abbott m2000 and ThermoFisher ABI7500 diagnostic instruments (used for RT-PCR) are located throughout this network. The number of locations that use these instruments across the U.S. is extensive, with the majority of Abbott m2000's located in academic and medical center laboratories. In addition, the Cepheid GeneXpert System diagnostic platforms are also widely distributed throughout medical centers (both larger and smaller community-based centers). Cepheid instruments are the “workhorse” of small to mid-sized metropolitan service areas and especially the smaller medical centers located in rural or remote hospitals. These instruments provide accurate results in less than an hour and can be performed in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high and moderate complexity tests.
- **Public Health Laboratories:** These laboratories focus on the identification and surveillance of infectious diseases and the health status of population groups. They perform more limited diagnostic testing, reference testing, and disease surveillance. In resource-poor areas, they provide testing of last resort. Personnel at these labs also provide emergency response support, perform applied research, and conduct training for laboratory personnel. State public health laboratories use a variety of diagnostic extraction and polymerase chain reaction (PCR) platforms to conduct nucleic acid testing. By order of prevalence, the primary extraction platforms used in public health laboratory settings include the Roche MagNA Pure, QIAGEN QIAcube, QIAGEN EZ1 XL,

ThermoFisher KingFisher, BioMerieux easyMAG, and Perkin Elmer Chemagic 360 systems. Similarly, the predominant PCR platforms or combination extraction/PCR platforms include ABI 7500 fast DX, ABI Quantstudio DX, Cepheid Gene Expert, BioFire 2.0/Torch, Hologic Panther, ABI 7500 Fast, Abbott m2000, QIAGEN Rotogene, Roche Light Cycler 480, and BD Max. Finally, many public health laboratories also have various platforms to perform rapid tests, such as the Abbott ID NOW, serological testing, such as the Abbott Architect, and antigen detection tests, such as the Quidel Sofia.

- **Point-of-Care Testing:** These tests are considered relatively easy and safe to use, and are performed on instruments that are primarily located in physicians' offices and urgent care facilities. During the COVID-19 public health emergency, the Centers for Medicare & Medicaid Services (CMS) will permit a Certificate of Waiver laboratory to extend its existing certificate to operate a temporary COVID-19 testing site in an off-site location, such as a long-term care facility. The temporary COVID-19 testing site is only permitted to perform waived tests, consistent with the laboratory's existing certificate and must operate under the direction of the existing lab director.

These instruments are routinely used to test for Streptococcal Pharyngitis ('strep throat'), influenza, and human immunodeficiency virus (HIV). Examples of these types of assays include the Abbott ID NOW COVID-19 molecular test and the Quidel Sofia 2 SARS FIA antigen test. Approximately 350,000 Abbott ID NOW tests are currently available on the commercial market each week. The Quidel antigen test production is currently approximately 1 million tests per week and is projected to increase to over 2 million tests per week on the commercial market in the next month. While some of these tests are point-of-care and can provide a result within 5-15 minutes, they are low throughput, meaning that only a limited number of tests can be performed each hour. Also, their sensitivity to detect virus is generally lower than that of the other types of tests, so it is possible that some people could test negative when they really are virus positive (false negative). While this is possible with all tests, it is somewhat more likely with point-of-care tests.

The Federal government has worked intensively with each component of the laboratory ecosystem. Beginning in March, the Biomedical Advanced Research and Development Authority (BARDA) invested in adding SARS-CoV-2 tests to diagnostic systems that are now used in commercial and clinical laboratories in order to rapidly expand high-throughput and near-patient/hospital-based diagnostic testing capacity. The Federal government has worked with manufacturers to increase available inventory, gain insight into diagnostic instrument install bases, and procured and distributed collection supplies. As of May 19, 2020, the Food and Drug Administration (FDA) has worked with test developers and laboratories to grant 104 EUAs. In addition, more than 250 laboratories began testing under the regulatory flexibilities adopted in the Center for Devices and Radiological Health March 2020 guidance (updated in May 2020).

HHS and the Federal Emergency Management Agency (FEMA) have worked to remove production barriers and provide guaranteed orders to de-risk production and investments. CDC has supported the national clinical laboratory network through promulgation of guidance, hosting webinars, and advancing additional training. As a direct result of these actions, the Federal government estimates that more than 28 million laboratory tests could be performed in May and a similar number of tests could be performed in June.

How Much Testing is Sufficient?

The nation has now performed over 12 million nucleic acid tests, with more than two million tests completed each week; and the numbers continue to grow. The rates of testing vary widely by state, with states experiencing the worst outbreaks generally performing substantially more tests than states less affected.

Estimates about how many tests are needed vary widely based on assumptions such as the prevalence of active cases, the number of contacts per case, the effectiveness of mitigation in the community, the sensitivity of the assays to detect cases, and the overall level of immunity within the community. Estimates in the literature vary from a few hundred thousand per day to twenty million per day. For example, the simulation model^{vi} developed by the Safra Center at Harvard assumes: tests are 80% sensitive (actual average sensitivity of laboratory based nucleic acid detection test is 95%); hospitalization rate is 20% (actual hospitalization rate is <5%); no effect of mitigation (actual at least 35%); days to recovery is 15 days (actual is 11 days or less). If testing can be targeted to likely positive individuals ($f = 10$), the actual number of tests needed per day is reduced from Safra's estimate of more than three million to just over 300,000 if the correct assumptions are used. This number is already being achieved through the current testing regimen, and will be far exceeded by mid-summer.

The authors of the *National Covid-19 Testing Action Plan: Pragmatic steps to reopen our workplaces and our communities*, a report from the Rockefeller Foundation, suggested that U.S. needed to increase capacity for testing to three million tests per week as soon as possible – a number that closely matches states' goals for May and June (see below). In order to grow U.S. testing capacity from three million tests per week to over 30 million per week, they recommended investing in a Testing Technology Accelerator. This accelerator would rapidly scale up testing utilizing a mix of current and newly developed technologies. This recommendation aligns perfectly with the Federal government's strategy: to maximize the numbers of current tests while coordinating with the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx) Program, BARDA, and Defense Advanced Research Projects Agency (DARPA) efforts to incorporate new, high throughput, high performing tests into the national strategy once developed. Additional information about these efforts can be found in the increasing testing capacity section of this document.

Modeling efforts for COVID-19 have focused on working across the Federal government and with non-federal partners to provide the most accurate, robust, and timely data available for

response decision making. HHS and our partners have created models to inform every aspect of the Federal government’s response, including potential trajectory of virus spread at the national and state level, and projections related to the potential impact of mitigation strategies on both health outcomes and associated resource utilization. A series of compartmental models of COVID-19 transmission were developed to assess the potential impact of different intervention strategies (e.g., social distancing strategies, changes to travel patterns, vaccines).

Modelers have quantified modeled outcomes both in terms of health outcomes (e.g., incident infections, persons hospitalized, mortality) and associated resource utilization (i.e., personal protection equipment (PPE), critical care beds, ventilators). Models also estimated the number of COVID-19 cases, adjusted for treatment seeking behaviors and testing practices in the U.S. These analyses help inform decision making at the Federal level, including determinations for the number of tests that may be necessary, and are also shared with states via regular modeling updates at meetings of the Council of State and Territorial Epidemiologists (CSTE). These data are made available to the public via CDC website postings.

Positivity Rate

Many epidemiological modelers and major public health organizations including WHO have set an objective that the proportion of positive test results (percent positive) should be 10 percent or less.^{vii} This is a “common sense” type of metric that is easily understood. If 20 percent or 30 percent of the tests are positive, you are likely missing many positives as well as their contacts. If only 10 percent are positive (or less), then you are likely testing enough to assure broad coverage of the population.

Although 10 percent is not itself a “magic number,” it is a nearly universally suggested at least as a first estimate of sufficiency of testing. Therefore, every day the Federal government assesses its overall performance and that of each state to this metric.

Based on the data available from May 8 to May 15, 2020, the U.S. positivity rate averaged over that seven-day period **is now 7.5 percent** and is continually decreasing. The percent positive among results originating from the three major laboratory types for this period are listed in the table below:

Laboratory Type	% Positive
Hospital Labs	6.98%
Commercial Reference Labs	7.79%
Public Health Labs	8.23%
TOTAL U.S.	7.5%

Disaggregation of the data into individual states shows **41 states have already achieved the 10 percent positive or lower threshold (7 day averages)**, with the remaining states and the District of Columbia continuing to improve on a daily basis as testing increases. The jurisdictions with the highest positivity rates (D.C. and Maryland) are now below 20 percent, and each of these plans to perform four times their cumulative totals as of April 21 during May and June.

Interim State Plans

The Paycheck Protection Program and Health Care Enhancement Act requires each state or jurisdiction that is receiving funding for testing to submit to the HHS a specific testing plan, guided by ongoing technical assistance from the Department. Plans for May and June are due to HHS on May 30, and plans for remainder of 2020 are due on June 15.

As a precursor to these formal plans, HHS has provided each state with technical assistance to establish state goals and to help fully utilize its existing testing capacity. Specifically, a multidisciplinary Federal team with experts from the Office of the Assistant Secretary for Health (OASH), FEMA, CDC, and other agencies held calls with leadership from each state and territory. In general, state participants included a representative from the Office of the Governor, the state public health laboratory, the state health official, and the state epidemiologist – or their equivalents.

The outcomes of these calls were initial testing goals for each state for May and June, and detailed plans to maximize laboratory instrument capacity in each state with available testing reagents. The overall goals were determined by considering multiple factors, including the current rate of new cases, plans for mitigation, percent positivity, and other factors.

Table 1 provides a breakdown of the initial testing targets agreed upon by the States and the Federal team. As demonstrated, the overall target for the nation for the month of May (and June) is 12.9 million tests. On a state-by-state basis, the targets ranged from a minimum of 2% of the population tested, to 14.9% each month.

**U.S. Department of Health and Human Services
Report to Congress: COVID-19 Strategic Testing Plan**

STATE	ABBR.	POPULATION	STATE DATA		RECOMMENDED TARGET		
			TOTAL TESTS TO DATE April 21	TOTAL TEST TO DATE PER 1,000	TESTING TARGET	MAY TESTS PER THOUSAND	MULTIPLE TARGET VS. ACTUAL
ALASKA	AK	731,545	11,119	15	20,973	29	1.9
ALABAMA	AL	4,903,185	48,387	10	195,000	40	4.0
ARKANSAS	AR	3,017,804	27,204	9	90,000	30	3.3
ARIZONA	AZ	7,278,717	55,152	8	150,000	21	2.7
CALIFORNIA	CA	39,512,223	300,100	8	1,200,000	30	4.0
COLORADO	CO	5,758,736	48,704	8	195,000	34	4.0
CONNECTICUT	CT	3,565,287	64,192	18	200,000	56	3.1
DISTRICT OF COLUMBIA	DC	705,749	14,939	21	60,000	85	4.0
DELAWARE	DE	973,764	16,656	17	80,000	82	4.8
FLORIDA	FL	21,477,737	284,206	13	600,000	28	2.1
GEORGIA	GA	10,617,423	88,140	8	210,000	20	2.4
HAWAII	HI	1,415,872	25,579	18	30,000	21	1.2
IOWA	IA	3,155,070	27,615	9	60,000	19	2.2
IDAHO	ID	1,787,085	17,730	10	40,000	22	2.3
ILLINOIS	IL	12,671,821	154,997	12	620,000	49	4.0
INDIANA	IN	6,732,219	67,264	10	168,000	25	2.5
KANSAS	KS	2,913,314	19,101	7	60,000	21	3.1
KENTUCKY	KY	4,467,673	33,328	7	132,000	30	4.0
LOUISIANA	LA	4,648,794	141,835	31	200,000	43	1.4
MASSACHUSETTS	MA	6,892,503	175,372	25	700,000	102	4.0
MARYLAND	MD	6,045,680	73,635	12	300,000	50	4.1
MAINE	ME	1,344,212	14,943	11	60,000	45	4.0
MICHIGAN	MI	9,986,857	121,298	12	450,000	45	3.7
MINNESOTA	MN	5,639,632	47,697	8	190,000	34	4.0
MISSOURI	MO	6,137,428	56,986	9	200,000	33	3.5
MISSISSIPPI	MS	2,976,149	52,364	18	100,000	34	1.9
MONTANA	MT	1,068,778	11,241	11	45,000	42	4.0
NORTH CAROLINA	NC	10,488,084	83,331	8	300,000	29	3.6
NORTH DAKOTA	ND	762,062	14,987	20	45,000	59	3.0
NEBRASKA	NE	1,934,408	16,782	9	40,000	21	2.4
NEW HAMPSHIRE	NH	1,359,711	15,041	11	60,000	44	4.0
NEW JERSEY	NJ	8,882,190	185,914	21	750,000	84	4.0
NEW MEXICO	NM	2,096,829	40,877	19	150,000	72	3.7
NEVADA	NV	3,080,156	40,464	13	120,000	39	3.0
NEW YORK	NY	19,453,561	649,325	33	1,500,000	77	2.3
OHIO	OH	11,689,100	94,239	8	375,000	32	4.0
OKLAHOMA	OK	3,956,971	44,489	11	90,000	23	2.0
OREGON	OR	4,217,737	40,045	9	80,000	19	2.0
PENNSYLVANIA	PA	12,801,989	166,851	13	330,000	26	2.0
PUERTO RICO	PR	3,194,000	10,620	3	60,000	19	5.6
RHODE ISLAND	RI	1,059,361	39,333	37	158,000	149	4.0
SOUTH CAROLINA	SC	5,148,714	42,441	8	170,000	33	4.0
SOUTH DAKOTA	SD	884,869	12,815	14	50,000	57	3.9
TENNESSEE	TN	6,829,174	108,182	16	250,000	37	2.3
TEXAS	TX	28,995,881	205,399	7	750,000	26	3.7
UTAH	UT	3,205,958	72,358	23	135,000	42	1.9
VIRGINIA	VA	8,535,519	58,354	7	235,000	28	4.0
VERMONT	VT	623,989	13,111	21	30,000	48	2.3
WASHINGTON	WA	7,614,893	145,031	19	580,000	76	4.0
WISCONSIN	WI	5,822,434	52,461	9	210,000	36	4.0
WEST VIRGINIA	WV	1,792,147	25,435	14	100,000	56	3.9
WYOMING	WY	578,759	7,386	13	12,000	21	1.6
TOTAL		331,433,753	4,185,055	13	12,935,973	39	3.1

Table 1. Table columns from left to right are state name, State abbreviation, cumulative number of tests performed by state as of April 21, 2020; testing rate (tests per thousand people, cumulative); the suggested target number of tests following discussions with the Federal government; the testing rate for the month if the suggested target were met; and the ratio between the suggested target and the cumulative tests performed in that State.

Viewed another way, the graph below shows each state’s goal for testing per 100,000 population per month in May and June. The Federal government recommends all states to have an objective of testing a minimum of 2 percent of their population in May and June, pending additional new data on infections and impact of reducing mitigation.

FEDERAL-STATE TESTING PARTNERSHIP

Fully Supplied State Goals for May

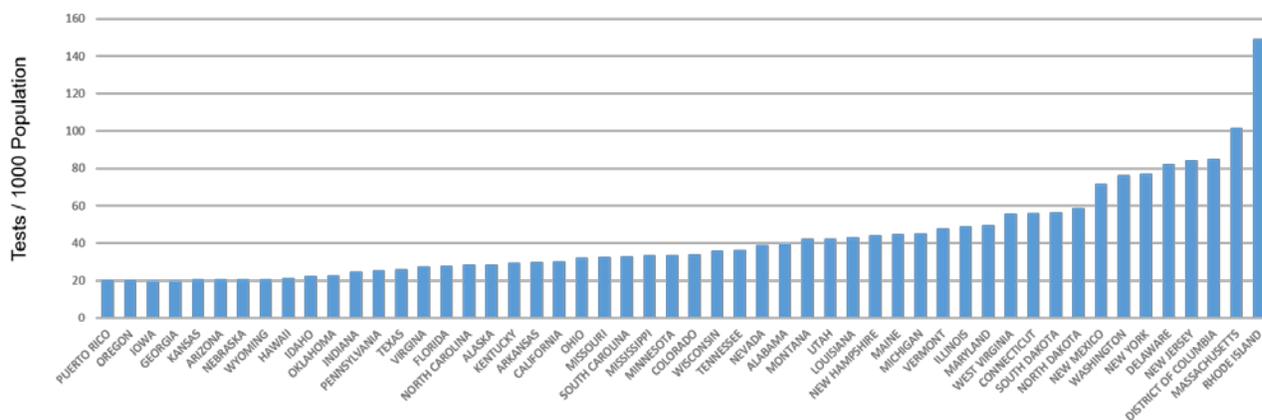


Figure 1. Fully supplied state testing goals for May

Testing for Special Populations

CDC and the White House Task Force are currently developing specific guidance on how, when, and if, viral and/or serologic testing should be considered as a component of reopening businesses and other institutions. The first set of recommendations was issued by CMS on May 18, after consultation with the Task Force and CDC, regarding specific recommendations for integration of testing in nursing homes (Appendix C). Specifically, CMS recommends that: “Nursing homes should have a comprehensive plan for testing. All residents should receive a single baseline test for COVID-19. Also, all residents should be tested upon identification of an individual with symptoms consistent with COVID-19 or if an employee or staff member tested positive for COVID-19.” In addition, “All {nursing home} staff should receive a baseline test, and continue to be tested weekly.” Until a point in time that the pandemic is controlled, or new data emerge, this type of aggressive regimen can optimally protect our most vulnerable within nursing homes. CDC and the Task Force are currently developing specific recommendations for how to integrate testing in other environments, including universities, critical infrastructure worksites, prisons, other congregate care facilities, and other environments. These will be forthcoming during the interval before the next Congressional report.

State Plans

State plans must establish a robust testing program that ensures adequacy of COVID-19 testing, including tests for contact tracing, and surveillance of asymptomatic persons to determine community spread. States must assure provisions are in place to meet future surge capacity testing needs including POC or other rapid result testing for local outbreaks. States should also include plans for testing at non-traditional sites (e.g., retail sites, community centers, residential medical facilities, or pharmacies); testing of at risk and vulnerable populations including the elderly, disabled, those in congregate living facilities such as prisons, and racial and ethnic minorities and other groups at risk due to high frequency of occupational or non-occupational contacts; testing of individuals engaged in critical infrastructure sectors, such as food and agriculture and healthcare workers, and will address any essential partnerships with academic, commercial, and hospital laboratories to successfully meet testing demand. In May, CDC awarded a total of \$10.25 billion to states, territories, and localities to be used to implement the goals of each jurisdiction's testing plan. States, territories, and localities will be expected to use these funds to purchase tests and related supplies, as necessary. See Appendix D for ELC Health Care Enhancement: 2020 Supplement, the guidance to States on submitting State plans.

Although a number of State-specific factors will determine quantitative objectives, States are requested to detail how a minimum of two percent of the State's population will be tested each month beginning immediately; as well as plans to increase that number by the fall of 2020. States are requested to include a list of laboratories that will be testing in their State, along with each laboratory's available platforms and throughput.

Once submitted, a multidisciplinary team of experts from HHS will thoroughly review each State's plan to ensure that the testing plan is sufficient to mitigate the spread of the virus, protect vulnerable groups, and accounts for enough testing supplies and reagents to cover all groups including underserved populations. The review panel will be chaired by the Assistant Secretary for Health, and include subject matter experts that span the required disciplines, including membership from the Laboratory and Diagnostics Task Force within the Office of the Assistant Secretary for Health, NIH, CDC, and other subject matter experts. The panel will also review State testing progress, needs assessment, and plans on a monthly basis to determine if modifications to the plan are required, or additional assistance is needed. Modifications to the State plans may be necessary if patterns of virus transmission change or are projected to change, increased case rates are observed, and/or additional types of testing and inventory become available through the RADx program at NIH or other sources.

Testing Goals beyond June 2020

By September, the nation will be capable of performing at least 40-50 million tests per month. This includes approximately 25 million POC tests, including new SARS-CoV-2 antigen tests. Acceleration of laboratory testing – even with current platforms – could result in even higher numbers of tests available.

HHS will re-evaluate goals and objectives for the remainder of 2020 based on the testing plans developed by States as well as the ongoing epidemiology of COVID-19. HHS will continue to aggressively support and conduct programs such as RADx (detailed in the Increasing Testing Capacity section of this report) to accelerate the development and commercialization of new COVID-19 diagnostics for the Fall, which could add to this overall number – or improve the performance of the testing at this numeric level.

Federal Government Support to States

To enable States to achieve the testing goals developed in coordination with the Federal government, the Federal government has worked with manufacturers to gain insight into diagnostic instrument install bases; procured and shipped collection supplies; and determined reagent inventory. The Federal government then provided all information to States so they could better determine how to optimize their testing strategy. The Federal government also purchased and allocated POC devices and tests; developed, implemented, and facilitated community-based testing sites across the country; and provided significant guidance and technical assistance for State plans. The increase in the numbers of tests performed since early March is a direct reflection of these efforts. Moving forward, jurisdictions should use the \$10.25 billion recently provided to states, territories, and localities by the Federal government to support the purchase of tests and related supplies, personnel for contact tracing, and reporting infrastructure, etc., for their jurisdictions, as needed to fulfill their approved testing plans.

Diagnostic Platform Capacity

Prior to setting State goals, Federal government research determined the number and type of high and low throughput laboratory platforms in each State, including their total capacity to perform COVID-19 tests if utilized to 100 percent capacity. Each governor received the specific location, type of instrument, and when possible, the actual utilization of that instrument. Figure 2 is a map that shows the general location and type of diagnostic instrument, but does not disclose specific addresses or proprietary information. The map does not include the distribution of Abbott ID NOW POC devices. There are now more than 18,000 of these widely dispersed throughout the nation, including at public health laboratories in each State. It also does not include the Quidel Sofia 2 POC instruments, for which there are now more than 20,000 available nationwide.

The total capacity of these machines exceeds 200 million tests per month, if they were entirely dedicated to COVID-19 testing. As a result of this analysis, it was determined that each State had

the capacity to meet its testing goals internally, although four States did not have excess capacity and would likely require outside assistance. For these States, alternate plans including the utilization of national reference laboratories, such as LabCorp and Quest, were suggested and implemented by these States.

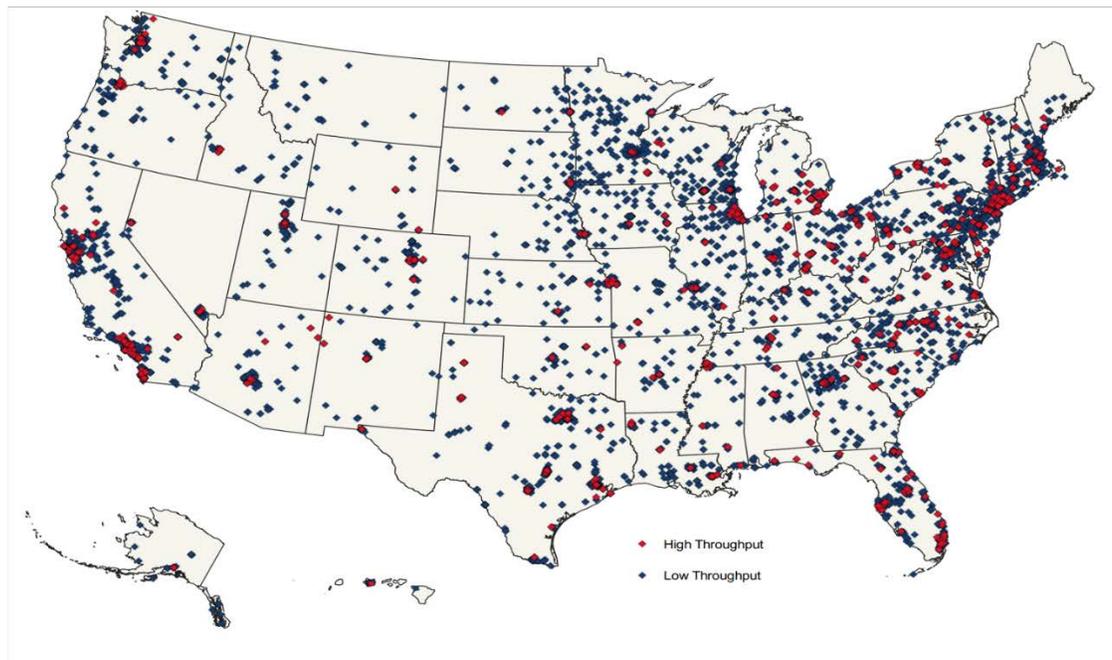


Figure 2. Lab Testing Capacity: General location and type of diagnostic instrument

Collection Supplies

To ensure States meet their testing goals, the Federal government procured FDA authorized swabs and transport media, and is distributing these supplies to a single location in each State determined by the Governor's office. For May, the Federal government will distribute 12.9 million swabs and 9.8 million tubes of transport media to the States. If States surpass their testing goals for May, additional collection supplies are available for limited federal supplementation if states cannot otherwise procure these supplies. The Federal government procurement still represents much less than half of the overall U.S. commercial market availability, so States can continue to procure supplies on their own. In addition, testing performed by major reference labs provide their own supply of tubes and media. The Abbott ID NOW point-of-care and Quidel tests also come complete with swab and reagents. Based on the Federal government procurements and the availability of specimen collection supplies in the private marketplace, there will be sufficient collection supplies to meet State needs.

To ensure that States have the collection supplies that they need through December 2020, the **Federal government plans to acquire 100 million swabs and 100 million tubes of viral**

transport media, and distribute these supplies to States as requested to meet their individual State plans. This large-scale acquisition reflects a significant expansion of current capacity and is a result of the broadening of available swab and media types authorized by the FDA and use of Title III of the Defense Production Act (DPA) to increase production of swabs.

Specifically, the Department of Defense (DoD) is investing \$75.5 million in DPA Title 3 funding to increase swab production by 20 million swabs per month starting in May. Puritan Medical Products, which was awarded the contract, will quickly establish a new manufacturing facility capable of doubling its current monthly output of 20 million swabs (to 40 million). The increased production and long-term industrial capacity will help support the needs of the nation.

A diagram outlining the flow of swabs and media to the States, labs and providers offices is included in Figure 3 below:

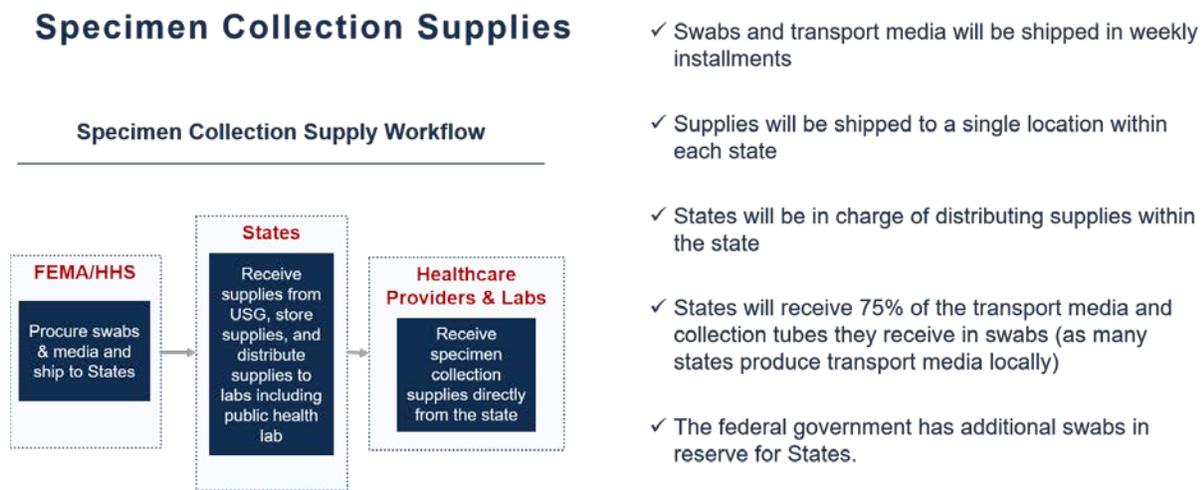


Figure 3. Specimen collection supply workflow

Reagents

Research performed by the Federal government has indicated that there will be at least 28 million tests available in the U.S. market in May, with that number growing substantially over the coming months.

Table 2. Available testing reagents (May 2020)

Company	Available May Tests
COMPANY 1	2,300,000
COMPANY 2	360,000
COMPANY 3	1,500,000
COMPANY 4	4,900,000
COMPANY 5	2,500,000
COMPANY 6	3,200,000
COMPANY 7	1,400,000
COMPANY 8	12,000,000
TOTAL	28,160,000

Although these tests numerically exceed the overall goal of States, not every test is available in unlimited supply to States that may want that specific test. To solve this issue, the Federal team has assisted each State to match their capacity with the reagents that are available; and conversely, the Federal government has assisted industry to develop a distribution strategy to meet the demands of each State. For example, a large availability of ThermoFisher TaqPath COVID-19 tests led to a shift in testing strategies such that States would utilize this platform preferentially, at least until inventory for other platforms became increasingly available. The dynamic nature of testing availability will be complemented by additional regulatory action to expand the number of platforms compatible with the available tests, as the FDA did recently for the ThermoFisher TaqPath COVID-19 Combo Kit.

As opposed to collection supplies, reagents are typically manufactured by larger companies with efficient distribution channels. Therefore, there was no justification for the Federal government to purchase reagents and then redistribute them. Instead, the Federal government has assured allocation through pre-existing distribution channels.

Allocation of Abbott ID NOW Point-of-Care Tests

At the end of March, the FDA issued an EUA for Abbott’s ID NOW POC test for SARS-CoV-2, which is capable of being run on any of the more than 18,000 ID NOW portable instruments currently available in the United States. Within a week after FDA issued the EUA, the company delivered approximately 350,000 test kits per week.

The ID NOW test can deliver positive test results in as soon as five minutes, with negative test results taking no longer than 15 minutes. Moreover, the test does not require additional materials, swabs, or reagents—each test comes complete with everything needed for use, and is

performed in a CLIA-waived laboratory setting, meaning the test can be performed in a laboratory or POC setting that has or is associated with a CLIA certificate.

However, the test is low throughput (about 4 tests per hour) so it is not suitable for screening thousands of individuals in an outbreak. Additionally, the test is designed to go from “nose to instrument,” meaning that the test loses sensitivity if the swab is placed in media and then transported to a distant site for testing, increasing the potential for a false negative result.

As such, the Federal government assessed, and acted upon the fact, that this testing platform was uniquely suited to remote locations where there is no other testing infrastructure, as well as for the investigation of outbreaks where an answer is needed immediately, such as in nursing home outbreaks or other congregate living situations.

To ensure the availability of this unique resource for these applications, the Federal government purchased ID NOW instruments and distributed 15 instruments to at least one public health lab in each State; 50 to the public health labs in Alaska (because of the State’s vast geography and remote locations); 250 instruments to the Indian Health Service (IHS); and a smaller number of instruments to U.S. Pacific Islands. Additionally, instruments were deployed in support of specialized missions including the Department of Energy (DoE) and other critical infrastructure.

In addition to the instruments themselves, the Federal government acquired 100,000 of the available 350,000 tests weekly, to ensure distribution of tests for these critical needs. Although the distribution varies somewhat by week, in general each week 60,000 tests are for the public health labs, 20,000 per week to IHS, and 10,000 per week for the Federal Bureau of Prisons. A portion of these tests are stored in the Strategic National Stockpile for use in crises that require a rapid response, such as outbreaks in meatpacking plants. The remainder of the tests support Federal partners, including the Veterans Administration, Department of Justice, DoD, Department of Homeland Security, and Department of Energy, as well as FedEx and UPS in implementing Project Airbridge to transport PPE from other countries to the U.S.

To date, HHS has provided more than 297,000 test kits to public health labs in every State and territory, and nearly 110,000 test kits to the IHS for distribution throughout tribal communities.

Quidel Sofia 2 Instrument and Tests

Quidel has recently received an EUA from the FDA for the Sofia 2 SARS Antigen FIA, a rapid POC test (results within 15 minutes) that is performed on the Sofia 2 fluorescent immunoassay analyzer. There are approximately 26,000 Sofia 2 instruments across the nation. Most of these units are located in provider and clinic settings. Because the Sofia 2 platform is small and mobile and the assay could be very useful, especially to diagnose persons who are positive for the virus in a community, industrial, or long-term care environment, the Federal government may purchase a quantity of these devices and tests to support specific outbreak investigations.

Community Based Testing Sites

Collection of specimens can occur within hospitals, at provider's offices, at public health laboratories, and other venues. To ensure that specimens could be collected without overburdening the traditional health care system, the Federal government implemented – beginning March 20 – Community Based Testing Sites (CBTS) and progressively developed these prototypes such that they are now widely available for use as part of each State's testing plan.

The Federal government worked with State and local partners to establish federally supported CBTS sites in locations prioritized by the CDC. The CBTS model was developed for States, local public health agencies, healthcare systems, and commercial partners as they work together to stop the spread of COVID-19 in their communities, focusing initially on healthcare facility workers and first responders. The CBTS federally supported, State managed, locally executed model has been a profound success, testing to date, approximately 200,000 individuals.

The current CBTS model has nine core components: (1) Registration, (2) Ordering the test, (3) Self-swabbing, (4) Specimen handling, (5) Specimen Storage & Shipment, (6) Lab processing, (7) Patient Notification, (8) Logistics, and (9) Reporting.

For these initial sites, the Federal government provided a Federal physician who orders all of the COVID-19 tests, the Federal contracts for shipping the specimens, laboratory processing, patient notification, and logistics (to include supplies, personal protective equipment, language translation services). The Federal government also utilized U.S. Public Health Service personnel to provide data management, safety and quality control checks at each site.

Since the onset, the federally supported CBTS program has led advanced testing innovations, such as the implementation of nasal self-swabbing, which has minimized the need for trained healthcare professionals and PPE. These advances increased access to testing supplies by broadening the variety of swabs authorized, and between April 10-15, 20 States transitioned their sites to State control, allowing for more flexibility in testing and reporting. In order to provide additional testing support, the CBTS Task Force continues to support 14 sites in five States.

The Federal government will continue supporting each public site until the site is ready to transition to State-management. When the site is ready, the Federal government will support the transition process to ensure States can fully manage and operate their CBTS locations independently. This includes providing each site with enough supplies to continue to operate for 7-14 days after the agreed upon transition date.

Building on the initial success of the CBTS model, the Federal government next leveraged public-private partnerships with pharmacy and retail companies (CVS, Health Mart, Kroger, Rite Aid, Walgreens, and Walmart) to accelerate testing for more Americans in more communities across the country. The public-private partnership model operates on the federally supported, State managed model; but the private partner is responsible for providing the nine components.

The Federal government provides each of the private partners with a bundled payment. The partnership builds on the experience gained from pilot sites, and:

- Provides Americans with faster, less invasive and more convenient testing
- Protects healthcare personnel by eliminating direct-contact with symptomatic individuals
- Expands rapidly to areas that are under-tested and socially vulnerable

In determining the site selection for the retail testing locations, the Federal government focused on communities with high social vulnerability using the CDC's Social Vulnerability Index (SVI) as one of the main factors to select sites. The SVI measures the resilience of communities when confronted by external stressors along four main themes:

- Socioeconomic Status
- Household Composition & Disability
- Minority Status
- Housing Type

The public-private partnership-testing model has resulted in testing of over 320,000 individuals at 408 sites in 44 States and the District of Columbia, with a goal to have over 416 sites by the end of May 2020. Sixty-nine percent of these sites have at least a moderate SVI and 31% have a high SVI.

Private retailers have also responded to the incentives created by the Federal government and have exponentially expanded their testing capacity. CVS has announced they will be establishing 1,000 testing sites throughout the nation outside of the public-private partnership.^{viii}

Testing Guidelines

CDC is responsible for providing guidance for States, local governments, and tribal governments on priorities for COVID-19 testing for active infection. According to the guidance "Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19)", the highest priority groups for testing include hospitalized patients with symptoms; healthcare facility workers; workers in congregate living settings, first responders with symptoms; residents in long-term care facilities or other congregate living settings, including prisons and shelters, with symptoms.^{ix} The next highest priority group includes persons with symptoms of potential COVID-19 infection, including: fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea, and/or sore throat; and persons without symptoms who are prioritized by health departments or clinicians for any reason, including but not limited to: public health monitoring, sentinel surveillance, or screening of other asymptomatic individuals according to State and local plans.

CDC has specific guidance on "testing considerations for nursing homes."^x Increased availability of testing in nursing homes has the potential to not only describe the scope and magnitude of

outbreaks, but also to help inform additional prevention and control efforts designed to further limit transmission among nursing home residents and health care professionals. This guidance is frequently updated based on lessons from the field, new science, and modeling work. CMS recently released “Guidance on Reopening Nursing Homes” that also includes information on testing for nursing homes as part of safely re-opening.^{xi} The CMS guidance recommends a facility should have a testing plan based on contingencies, and, at a minimum, include the following components:

- The capacity for all nursing home residents to receive a single baseline COVID-19 test. All residents are tested upon identification of an individual with symptoms consistent with COVID-19, or if staff have tested positive for COVID-19. Weekly re-testing continues until all residents test negative;
- The capacity for all nursing home staff (including volunteers and vendors) to receive a single baseline COVID-19 test, with re-testing every week;
- Written screening protocols for all staff (each shift), each resident (daily), and all persons entering the facility, such as vendors, volunteers, and visitors;
- An arrangement with laboratories to process tests. The test used should be greater than 95% sensitive, and greater than 90% specific. Also, serologic tests should include a confirmatory serological assay that includes an epitope from the spike protein for specimens with a positive initial test; and
- A procedure for addressing residents or staff that decline or are unable to be tested (e.g., symptomatic resident refusing testing in a facility with positive COVID-19 cases should be treated as positive).

Other vulnerable populations can be prioritized for testing as per State and local testing plans. State and local health departments may adapt this guidance to support the development and implementation of their plans for reopening and in response to rapidly changing local circumstances.

Critical Infrastructure

Guidance on surveillance strategies and controls has also been issued to mitigate risk of transmission among workers within critical infrastructure sectors.^{xii,xiii,xiv} There are 16 critical infrastructure sectors whose assets are considered so vital to the U.S. that their incapacitation or destruction would have a debilitating effect on security, national economic security, national

public health or safety, or any combination thereof.^{xv} Within the emergency services and healthcare and public health sectors, the increased level of exposure suffered by first responders has resulted in large numbers of infections among critical workers in these sectors.^{xvi} Similarly, the food and agriculture sector has been negatively impacted by essential workers being diagnosed with COVID-19.^{xvii}

Ensuring the sustainability of critical infrastructure sectors is one of the foundational aspects of the President’s *Opening Up America Again*, and one of the proposed gating criteria for reopening is a robust testing strategy for workers in critical infrastructure sectors. The Federal government will work with States, as needed, to develop and implement tailored testing and surveillance solutions to the challenges faced by critical infrastructure sectors. This may include the use of targeted testing in response to outbreaks in work settings, by using a testing strategy to identify infected employees, conduct contact tracing, and implement measures to prevent transmission.

Continued cooperation between HHS and manufacturers will also continue to play an integral role in providing timely updates to available guidance documents, recommendations for use of specimen collection supplies, and the anticipated increase in serological testing.^{xviii,xix}

- | |
|--|
| <p>Critical Infrastructure Sectors</p> <ul style="list-style-type: none">• Chemical• Commercial Facilities• Communications• Critical Manufacturing• Dams• Defense Industrial Base• Emergency Services• Energy• Financial Services• Food and Agriculture• Government Facilities• Healthcare and Public Health• Information Technology• Nuclear Reactors, Materials, and Waste• Transportation System• Water and Wastewater Systems |
|--|

Increasing Testing Capacity

Increasing testing capacity is essential to improve the availability of tests, and access to testing resources needed for implementing robust diagnostic testing plans, timely monitoring systems, and rapid response programs. In order to successfully increase testing capacity, efforts must be holistic, to include cooperative planning and prioritization across Federal, State, and private sectors. Additionally, the focus must be not only on the development and production of commercially available diagnostic assays, but also on the myriad of components necessary to support the testing enterprise, including instruments, supplies, PPE for healthcare and laboratory personnel involved in sample collection and testing, and the underlying regulatory, laboratory, and commercial systems that can:

- leverage the full spectrum of Federal regulatory functions,
- expand the available landscape of acceptable specimen collection and laboratory supplies and reagents,
- maximize use of available laboratory infrastructure and testing venues, and
- strengthen and support State-level testing and surveillance strategies.

Coordination with Private Sector

The Federal government, through the Laboratory Diagnostic Testing Task Force, has engaged in close coordination with commercial manufacturers and laboratories to gain a better understanding of supply chain challenges and projected inventory. In addition, HHS has worked diligently with these same manufacturers and laboratories to alleviate supply chain issues, increase test production, and testing capacity. HHS and FEMA have procured swabs and viral transport media (VTM) necessary for COVID-19 upper respiratory specimen collection, and are currently providing these materials directly to States for storage and distribution, in support of State-specific testing plans. In addition, the Federal government has utilized the DPA to increase production of swabs in the U.S. and alleviate the reliance on manufacturers overseas.

Additional Federal efforts to increase COVID-19 testing capacity will capitalize on the momentum gained from the regulatory, supply chain, and public-private partnerships accomplishments to date; as well as build momentum in additional areas, including optimizing alignment of laboratory capacity with testing demand, and strengthening testing in underserved and vulnerable populations. HHS will continue to work across the Department and with our other Federal, State, and local partners to ensure availability of appropriate testing platforms (e.g. rapid POC tests and lab-based assays). With federal technical assistance, assurance of the supply chain, and translation of innovations into the national diagnostics ecosystem, states will be able to ramp up testing and related efforts through the \$10.25 billion provided by CDC to states, territories, and localities. These funds will be used to implement jurisdiction-specific testing plans, including procurement of necessary tests and related supplies, implementation of contact tracing, and other required components. In addition, through technical assistance, the Federal Government will help support State testing plans and ensure the availability and access to testing for vulnerable populations and facilities that are at greater risk from the pandemic (e.g. healthcare workers and first responders; workers in meatpacking plants; long term care facilities; and underserved populations).

Regulatory Action

Early on during the SARS-CoV-2 pandemic, the Federal government took steps to increase testing capacity through regulatory action. The FDA provided crucial guidance for manufacturers to help accelerate the availability of COVID-19 tests^{xx}, and expanded of the number of authorized specimen collection supplies (e.g. swabs, viral transport media) and laboratory testing kits and reagents. FDA expanded the types of swabs and transport media acceptable for specimen collection, directly increasing the available inventory at the national level, and expanding the types of specimens acceptable for testing. These actions increased specimen collection throughput, while reducing both patient discomfort and the need for PPE utilization.

Between February 4 and May 5, FDA's actions have resulted in EUAs issued for 76 molecular tests and 12 serology tests.^{xxi} These authorizations included commercial manufacturers with instruments and systems in place in laboratories around the country, point-of-care tests, and

various types of sample collection. These actions not only increased the laboratory capacity for COVID-19 testing, but also provided valuable quality assurance for laboratories that purchase those tests.

As depicted in the following table 4, CMS has also taken significant action to ensure testing is accessible.

Table 3. CMS Regulatory Actions to ensure testing availability

CMS Focus Area	Description
COVID-19 Diagnostic Testing	<ul style="list-style-type: none"> Physician or non-physician practitioners are eligible for payment for assessment and specimen collection for COVID-19 testing using the level 1 evaluation and management code CPT code 99211. In light of the public health emergency, Medicare will recognize this billing code for all patients, not just established patients. This approach helps physician practices to operate testing sites during the PHE. In addition to practitioners, outpatient departments of hospitals will have a new code, CPT code C9803 under the OPSS for HOPDs to bill for a clinic visit dedicated to specimen collection and adopting a policy to conditionally package payment for this code. The OPSS will make separate payment for HCPCS code C9803 under the OPSS when no other primary service is furnished in the same encounter.^{xxii} Medicare will pay the higher payment of \$100 for COVID-19 clinical diagnostic lab tests making use of high-throughput technologies developed by the private sector that allow for increased testing capacity, faster results, and more effective means of combating the spread of the virus. A higher specimen collection fee will be paid to laboratories to travel to a Medicare beneficiary who is homebound or in a skilled nursing facility or in a home health to collect a specimen.^{xxiii} Several Medicare policies are being expanded, on an interim basis, to cover FDA authorized COVID-19 serology tests, to allow any healthcare professional authorized to do so under State law to order COVID-19 diagnostic laboratory tests (including serological and antibody tests), and to provide for new specimen collection fees for COVID-19 testing under the Physician Fee Schedule and Outpatient Prospective Payment System.²²
Physician or Practitioner Order for COVID-19 tests:	<ul style="list-style-type: none"> Medicare will not require an order from a treating physician or non-physician practitioner as a condition of Medicare coverage of COVID-19 diagnostic laboratory testing during the PHE. CMS similarly removed these requirements for an influenza virus and RSV diagnostic laboratory test that is necessary to establish or rule out a COVID-19 diagnosis. FDA requirements for an order and State requirements around ordering diagnostic tests would still apply. CMS has also removed certain documentation and recordkeeping requirements associated with orders for COVID-19 diagnostic tests as these requirements would not be relevant in the absence of an order. CMS still requires laboratories to furnish the results of COVID-19 tests to the beneficiary. Consistent and regular reporting of all testing results to local officials is critical to public health management of the pandemic; we would expect any clinician

**U.S. Department of Health and Human Services
Report to Congress: COVID-19 Strategic Testing Plan**

	<p>or laboratory receiving results to report those results promptly consistent with State and local public health requirements, typically within 24 hours.</p>
Pharmacists	<ul style="list-style-type: none"> Medicare will pay for COVID-19 tests performed by pharmacies that enroll in Medicare as laboratories. A pharmacist also may furnish basic clinical services, such as specimen collection, when performed under contract with a doctor or practitioner, in accordance with a pharmacist’s scope of practice and State law. As auxiliary personnel, pharmacists can provide services incident to the professional services of a physician or non-physician practitioner who bills Medicare Part B under the Physician Fee Schedule (PFS) services. If incident to rules under 42 CFR 410.26 are met and payment for the services is not made under Medicare Part D, the services must be provided in accordance with the pharmacist’s scope of practice and applicable State law. This can include working with a physician or non-physician practitioner to assess and collect specimens for COVID-19 diagnostic tests. A pharmacy that acquires a Clinical Laboratory Improvement Amendments (CLIA) certificate can enroll with Medicare as a clinical diagnostic laboratory to conduct and bill for clinical diagnostic laboratory tests authorized to be performed under its CLIA certificate.
Physician Self-referral Law (known as the “Stark Law”) Waivers	<ul style="list-style-type: none"> On March 30, 2020, CMS issued blanket waivers of the sanctions under the Stark Law. These blanket waivers apply to financial relationships and referrals that are related to the COVID-19 emergency. The remuneration and referrals described in the blanket waivers must be solely related to COVID-19 Purposes, as defined in the blanket waiver document. Under the waivers, CMS will permit certain referrals and the submission of related claims that would otherwise violate the Stark Law.

New and Emerging Technologies

As part of Stage 3 of the Testing Overview to support the reopening of America, the Federal government is partnering with the private sector to accelerate research and development of innovative tests, such as highly specific and sensitive serologic tests, antigen tests, POC nucleic acid tests, and tests using genomic sequencing technology. New and emerging technologies can help fulfill the need for testing capacity, by (1) making additional commercially available testing options available for Americans, (2) improving the manufacturing capacity for diagnostic tests, and (3) creating new testing approaches that may be easier to use, better prioritize those who need to be tested, and enable more efficient testing.

To date, nucleic acid testing has been the cornerstone of the Federal government’s diagnostic response to COVID-19. More recently, the FDA has granted EUAs for both antigen and serologic tests for COVID-19, increasing the numbers and types of diagnostic technologies in the toolbox. Over the next several months and as we move into influenza season, it will be critical that we work to validate new mechanisms to employ current technologies in innovative ways and support the development and scaling of new and emerging diagnostic tools. For example, pooling of samples from multiple (5, 10, or 20) individuals in a single test could yield dramatic advances for testing in circumstances where the overall prevalence of the disease is low (back to school, military missions, energy plants operations, etc.). However, pooling has not been validated to be accurate, and indeed, may compromise sensitivity of the assays. Validation of “pooling” techniques across multiple platforms including POC and laboratory-based tests will be performed and submitted to the FDA for authorization.

In addition, development, scaling and production of multiplexed assays (respiratory panels) should be prioritized as we head into influenza season. Multiplexed, multi-analyte diagnostic tests allow for the simultaneous detection of different analytes from a single specimen and are reagent sparing. For SARS-CoV-2, there are currently several multiplexed, multi-analyte reverse transcription polymerase chain reaction (RT-PCR) assays capable of detecting and differentiating SARS-CoV-2 from a panel of over 20 respiratory pathogens. These types of assays are critical for ensuring rapid, accurate diagnosis and differentiation of SARS-CoV-2 and influenza patients during influenza and respiratory virus season.

Other Emerging Technologies and Innovative Approaches

During times of pandemic when supply chains are strained by the traditional response, investing in emerging technologies and innovative supply approaches can further expand testing capacity by making tests simpler and easier to use for Americans. FDA recently authorized the first at-home sample collection kits. At-home sample collection and shipment to a dedicated laboratory means health care workers do not need to administer tests. This reduces health care worker burden and saves critical PPE. Making testing more available also slows the spread of infection by informing individuals who are currently positive for COVID-19. Promising emerging technologies include Next-generation Sequencing (NGS), Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), and adjunctive technologies.

NGS is a high-throughput deoxyribonucleic acid (DNA) sequencing technology that can be used to sequence the genetic code of a virus. NGS is a promising option for rapid-scale testing, utilizing infrastructure that already exists across the country. The resolution of NGS tests exceeds that of PCR-based tests.^{xxiv} In addition to providing diagnostic information, NGS can provide information about viral evolution and be utilized for additional drug and diagnostic assay development. In addition to monitoring mutations in the viral sequence (evolution), NGS can be used effectively in contact tracing programs, especially in areas with low transmission, to identify chains of transmission and to potentially identify new points or sources of introduction.

NGS has been used very effectively in the 2019/20 Ebola outbreak in DRC to identify silent chains of transmission.

However, NGS cannot be operated at POC and requires samples to be handled, transported, analyzed, and reported back to patients and health professionals. CRISPR technology can be used to identify a specific sequence in the viral genetic code and provide a detectable signal if the sequence is identified. This process has the potential to be done at home and without specialized equipment. These tests, however, are still not commercially available and will require time to develop and scale up. FDA recently authorized a CRISPR based assay that can reportedly test whether a patient sample contains SARS-CoV-2 virus in an hour.^{xxv} These tests should be prioritized for scaling given their lower dependence on complex supply chains.

Adjunctive technologies, or non-traditional diagnostic technologies, may be attractive because such capabilities may be rapidly deployable and empower the patient and health-care provider through remote and self-monitoring. Monitoring individuals prior to and in early stages of symptom onset (if symptomatic) can remove the barriers of testing largely performed at clinics and hospitals by identifying those who need to be tested and those who can remain quarantined or self-monitored. Such technologies include telemedicine or app-based technologies, wearables that can monitor patient vital signs data and algorithm-based tools that can predict or inform on risk of infection, severity or outcome. These tools may connect patients directly to health care professionals, which is beneficial in settings where resources are limited. A comprehensive solution instituted by BARDA includes leveraging the use of FDA-cleared technologies to monitor biophysical markers, as well as demonstrating capability to utilize wearable technologies such as smart watches to develop an ordinal symptom severity score to identify individuals who may be most at risk for severe cases of COVID-19. In addition, diagnostic tools developed to predict and inform on sepsis are being utilized in pilot studies of COVID-19 patients to potentially indicate risk of viral sepsis. Such innovations in digital health technologies could ultimately help reduce the time between infection and testing, provide information to improve clinical management of patients, identifying those who need additional care more quickly, and allowing individuals who test positive to self-quarantine sooner.

A key component of developing new testing technologies is tracking and ranking proposals. BARDA established the Medical Countermeasure (MCM) Portal for Coronavirus^{xxvi} to ensure Federal government partners could stay current with the rapidly evolving landscape of promising, emerging technologies. BARDA and interagency colleagues review and prioritize information and proposals from industry submitted to the portal. After the initial review “CoronaWatch” meetings are scheduled that allow interagency partners to evaluate and identify the best funding opportunities. As of May 1, 2020, the MCM Portal had received 2,590 applications that have resulted in over 250 CoronaWatch meetings, 99 of which were for diagnostics.

BARDA Investments

To support the anticipated need for expanded diagnostic capacity, BARDA has invested in the development of tests to detect active and prior infection for SARS-CoV-2. Beginning in March, BARDA invested in adding SARS-CoV-2 tests to systems that are routinely used in commercial and clinical laboratories, in order to rapidly expand high-throughput and near-patient/hospital-based diagnostic testing capacity. BARDA’s investments focused on “sample-to-answer” systems that do not require separate extraction reagents that had been in short supply. Six SARS-CoV-2 nucleic acid tests from five companies supported by BARDA received EUAs by April 3, 2020. Additional EUAs are expected in May. This, along with substantial increases in the number of diagnostics tests shipped by BARDA-funded test manufacturers, will further expand testing capacity.

As of mid-May, over 4.8 million diagnostic tests have been shipped by BARDA-funded test manufacturers for domestic use, and partners are continuing to increase production. BARDA has also invested in advancing development of POC nucleic acid tests, antigen tests, and serologic tests.

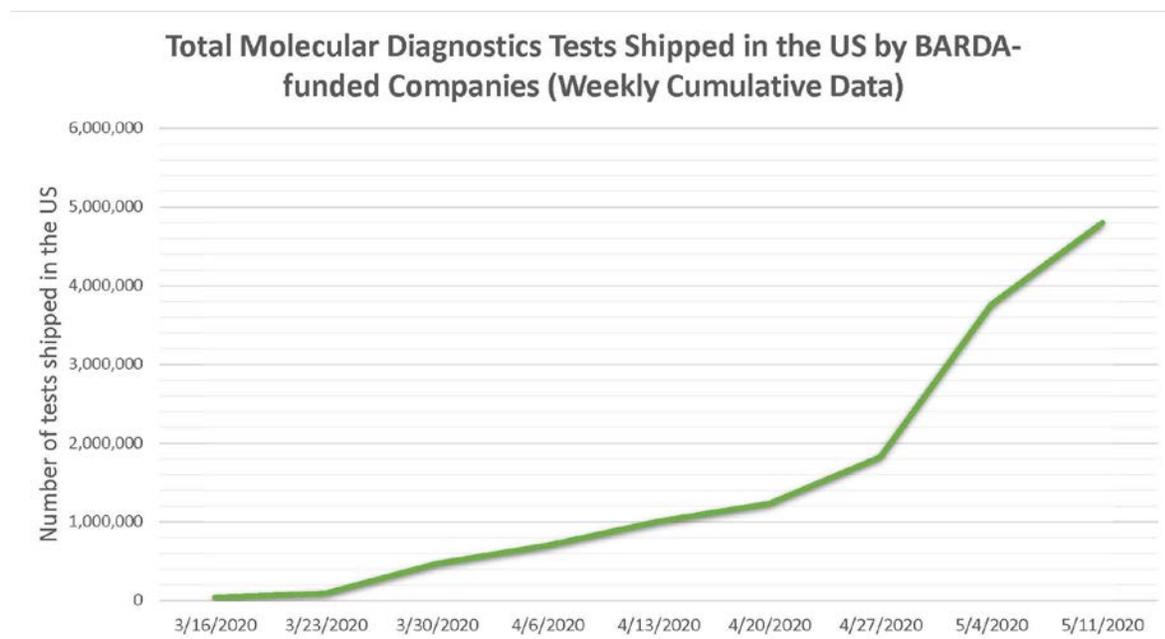


Figure 4. Molecular diagnostics tests shipped in the U.S. by BARDA-funded companies

In addition to the nucleic acid detection tests (RT-PCR and isothermal) that have been designed to detect SARS-CoV-2 ribonucleic acid (RNA) in respiratory samples, BARDA plans to support systems that integrate SARS-CoV-2 tests with tests for other respiratory pathogens. This will improve the efficiency and effectiveness of diagnosis of COVID-19, and rule-out of COVID-19 by diagnosis of other respiratory pathogens. Additionally, BARDA will leverage existing FDA-

cleared nucleic acid systems to develop pan-coronavirus assays that detect and differentiate coronaviruses. These tests will be useful in the current outbreak, and improve preparedness for emergence of other coronavirus in the future. BARDA will continue investments in molecular, antigen and antibody detection tests, focusing on laboratory and POC technologies that offer high sensitivity and specificity.

NIH Rapid Acceleration of Diagnostics (RADx-Tech) Program

The NIH will have an increasingly important role in the development of new diagnostic technologies and concepts of operation. The Assistant Secretary for Health will closely coordinate with the NIH leadership team for RADx to assure that new technologies developed will be seamlessly integrated into the testing ecosystem.

On April 29, NIH launched the RADx-Tech program to accelerate the development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improvements to clinical laboratory tests, that can directly detect SARS-CoV-2. The goal of this program is to support the development and deployment of tests with improved analytical and enhanced operational performance that improve access and reduce the cost of testing.

Technologies supported through this program will be sensitive enough to identify recently infected but asymptomatic individuals using a variety of sample types, such as nasal swabs, saliva, or blood, while being reliable with an easy to use design. Ease of use, including ability to integrate with mobile devices, and accessibility are key for the success of these potential new testing technologies.

The program has garnered interest from over 1,000 developers, with 79 full applications submitted within little more than a week of the program launch. Technologies will be put through a highly competitive, rapid three-phase selection process to identify the best candidates for at-home or point-of-care tests for COVID-19. During the first phase, experts in clinical, technical, business, regulatory, and manufacturing fields will rapidly assess the technology for potential. Promising technologies will advance to Phase I receive modest funding, and be matched with technical, business and manufacturing experts to increase the likelihood of success. Technologies that are already relatively far along in development can be immediately placed in Phase II, where support will be provided for scale-up tests for validation, meeting regulatory requirements, and supporting manufacture and distribution.

To ensure that innovations are available to the public as quickly as possible, NIH will leverage established partnerships with Federal agencies assisted by the coordination of the Assistant Secretary for Health. Partnerships include FDA, CMS, BARDA, and CDC, as well as commercial and private entities to propel technologies developed by RADx-Tech programs into widespread use. The goal is to make millions of accurate and easy-to-use tests per week available to all Americans by the end of summer 2020, and even more in time for the flu season.

Monitoring Testing Capacity

The ability to monitor, evaluate, and enhance current testing efforts is a key component of HHS testing initiatives. HHS maintains regularly updated datasets on a number of relevant testing metrics, including cases (national, State, and county data),^{xxvii} mortality reporting (national and State levels),^{xxviii} and testing (county, State, and national data).^{xxix} For several of these data, additional disaggregation by gender, race, ethnicity, and age is available to help monitor vulnerable populations. FDA offers useful data on the expansion of available diagnostic kits and laboratory tests by providing a regularly updated list of those tests that have received EUAs.^{xxx}

Vulnerable Populations

Although it is necessary to increase testing for the entire population, there are special populations that have historically been more difficult to reach for testing, such as those who are economically disadvantaged, speak English as a second language, or may be isolated, culturally or geographically. In addition, there are vulnerable populations that may be at increased risk of COVID-19. This can be a result of their occupation, as part of a critical infrastructure sector; through living conditions, such as in nursing homes or other congregate living situations; or through concurrent health conditions, such as those individuals who are living with HIV and need to maintain access to healthcare services. State's plans should address how the jurisdiction will meet the testing needs for vulnerable populations. The national strategy tailors approaches to reach each of these special populations. One of the critical parts of the strategy is to ensure at-need communities have access to testing. A significant number of HHS' diagnostic test investments continue to focus on technologies appropriate for use in the environments where these special populations need rapidly available tests, in non-laboratory settings, including tests such as small hand-held molecular tests and rapid antigen and antibody tests.

NIH is currently developing a program to expand testing capacity in underserved populations across the country. The RADx-UP (Rapid Acceleration of Diagnostics – Underserved Populations) program, part of the RADx initiative, will develop infrastructure to assess and expand evidence-based testing interventions and capacity for those populations that are disproportionately affected by, have the highest rates of, and/or are most at risk for adverse outcomes from contracting the virus. These populations include racial and ethnic minorities, rural populations, populations living in underserved urban areas, those in situations that facilitate transmission of the virus (e.g., assisted living facilities, nursing homes, jails/prisons, migrant worker communities), people experiencing homelessness, and those with underlying conditions. This program will establish pragmatic clinical trials at multiple sites across the country to investigate, in real-time, a variety of testing methods/approaches to better understand their uptake, administration, and effectiveness in specific populations, areas, or settings. Sites will collaborate with community health centers, houses of worship, homeless shelters, and prison systems to identify and address the unique needs of the different communities. Additionally, fully appreciating the scope of the sensitivities associated with this disease and the disparate toll COVID-19 is taking on specific populations, this initiative will build an ethical and social

implications program to understand the range of issues associated with testing/diagnostic technologies and information/data (including stigma associated with a positive test result) in research, clinical, or other settings.

Additionally, IHS is responsible for providing Federal health services to American Indians and Alaska Natives (AI/AN). There are many communities that benefit from IHS services, representing AI/AN populations on Indian reservations and Alaska Native villages as well as in rural, urban and remote settings. For these reasons, IHS was given priority access to rapid POC COVID-19 test systems as part of White House efforts to expand access to testing in rural communities. HHS will continue to work with IHS to ensure that the resources needed are available to support these communities with timely surveillance, detection, and response capabilities.

Resources for Testing

The Paycheck Protection Program and Health Care Enhancement Act (Public Law 116-139) was signed on April 24, 2020. The law includes \$100 billion for HHS in the Public Health and Social Services Emergency Fund (PHSSEF), which includes \$25 billion for testing, research and development, and response. This Act is the first piece of legislation specifically allocating funding for testing resources.

The HHS plan for use of the \$25 billion for testing, research, and development from this Act is outlined below.

Awards to IHS, States, Localities, Territories, and Tribes for Testing (\$11B)

The Act provides a minimum of \$11 billion to State, local, territory, tribe, or tribal (SLTT) organizations to develop, purchase, administer, process, and analyze COVID-19 tests, scale-up laboratory capacity, trace contacts, and related efforts. SLTTs are required by the Act to submit a testing plan to the HHS by May 23, 2020 that contains information on monthly testing needs, monthly laboratory and testing capacity, and how they will leverage testing resources to mitigate COVID-19 spread. Of these funds:

- \$4.25 billion is for allocation to States, localities and territories based on the number of COVID-19 cases;
- \$6 billion is for allocation to States, localities, and territories consistent with the population-based, Public Health Emergency Preparedness grant formula;^{xxxii} and
- \$750 million is for allocation to the Indian health care system, in coordination with the IHS; funds will be further allocated to IHS Healthcare facilities and programs, Tribal Health Programs, and Urban Indian Organizations using existing funding mechanisms.

**U.S. Department of Health and Human Services
Report to Congress: COVID-19 Strategic Testing Plan**

BARDA (\$1B)

The Act provides a minimum of \$1 billion for additional development, manufacture, and purchase of tests and diagnostics. BARDA plans to use funds to:

- Develop laboratory and point of care diagnostics, including antigen and antibody detection;
- Increase domestic test manufacturing capacity; and
- Increase sample collection kit production capacity.

CDC (\$1B)

The Act provides a minimum of \$1 billion for the CDC to implement testing, surveillance, epidemiology, laboratory capacity expansion, contact tracing, and public health data surveillance, and for analytics infrastructure modernization. CDC plans to execute the funds using contracts, grants, and other mechanisms to increase the public health response and build capacity, including:

- Increase technical assistance nationwide;
- Build laboratory capacity and strengthen clinical laboratory networks;
- Increase surveillance, detection, and data analytics; and
- Expand the electronic exchange of information between public health and health care.

FDA (\$22M)

The Act provides \$22 million for activities associated with diagnostic, serological, antigen, and other tests, and related administrative activities. FDA will use contracting vehicles and direct funding mechanisms to:

- Fortify personnel for review of diagnostics tests, prioritize review for test developers, and reduce the time it takes to review COVID-19 related submissions; and
- Develop sample panels and reference materials to accelerate the development and testing of diagnostic tests.

Health Resources & Services Administration (HRSA) (\$1.8B)

The Act provides \$1.8 billion for programs under the purview of, or managed with the coordination of the Department by, HRSA. This includes:

- \$600 million in direct, one time, formula based funding for health centers and Federally Qualified Health Centers to support testing;
- \$225 million for rural health clinics, which HRSA will execute in a similar manner as through the Provider Relief Fund; and
- Up to \$1 billion more for provider reimbursement costs related to testing of uninsured individuals, which will be executed in the same manner as funds for this purpose from the Families First Coronavirus Response Act (P.L. 116-127).

NIH (\$1.8B)

The Act provides a minimum of \$1.8 billion for NIH for point-of-care and rapid testing research and implementation, including:

- \$306 million for the National Cancer Institute (NCI) to develop, validate, improve, and implement for serological testing and associated technologies, including the evaluation of commercially available testing, clinical studies, and the establishment of centers of excellence in serological sciences;
- \$500 million for National Institute of Biomedical Imaging and Bioengineering (NIBIB) to support the RADx-Tech program, which is structured to deliver innovative testing strategies to the public as soon as late summer 2020; and
- \$1 billion for the Office of the Director to support activities including rapid scale up of diagnostics and community-engaged projects to expand testing of underserved populations.
 - The Act also provides transfer authority for the Director to move funds to other Institutes and Centers of the NIH. As of this date, the authority has not been used.

Other Resources (\$8.3 billion)

HHS will use any additional resources available to address emerging COVID-19 response needs. HHS' immediate planned use for these funds include:

- Purchase of rapid identification test kits for distribution across the US;
- Purchase of swabs and transport media to assist State and local testing efforts; and
- Serological testing demonstrations with health care workers and first responders.

Office of the Inspector General (OIG) (\$6M)

The Act directs \$6 million to OIG for oversight activities, which are to be available for obligation following consultation with the Appropriations Committees.

Resources from Prior Supplemental Appropriation Acts

In addition to the resources and planned use of testing funds outlined above, HHS resources from the prior three enacted supplemental (the Coronavirus Preparedness and Response Supplemental, the Families First Coronavirus Response Act, and the Coronavirus Aid, Relief, and Economic Security Act) also support testing, as described in detail in HHS spending plans (transmitted to Congress on April 3, April 17, and April 28 respectively).

While these activities are identified as directly supporting testing and diagnostic work, HHS funds to support State and local health departments, health system capacity building, provider reimbursement, pre and post market medical product testing, health surveillance, and other activities also support testing but are not described here in detail.

Amounts Available for Testing from Coronavirus Supplemental Appropriations

(\$ in millions)

Activity	Amount (\$M)
-	-
<u>Coronavirus Preparedness and Response Act (P.L. 116-123)</u>	
National Institutes of Health	
NIAID – Diagnostics	29
Public Health and Social Services Emergency Fund	
BARDA – Diagnostics	84
<u>Families First Coronavirus Response Act (P.L. 116-127)</u>	
Indian Health Service	
Testing for IHS and Tribally-operated Health Programs, and Urban Indian Organizations	64
Health Resources and Services Administration	
Payment of Claims for Testing of Uninsured	1000
<u>Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136)</u>	
National Institutes of Health	
NIAID – Diagnostics	30
NIBIB – Point-of-Care Test and Other Diagnostics Research	60
Public Health and Social Services Emergency Fund	
BARDA – Diagnostics	244
<u>Paycheck Protection Program and Healthcare Enhancement Act (P.L. 116-139)</u>	
Public Health and Social Services Emergency Fund	
State, Local, Tribal Awards	11000
BARDA	1000
Health Resources and Services Administration	
Payment of Claims for Testing of Uninsured	1000
Rural Health Clinics	225
Health Centers	600

Centers for Disease Control and Prevention	
Testing and Public Health Capacity	1000
Food and Drug Administration	
Funds for evaluation of testing	22
National Institutes of Health	
NCI - Serology Research	306
NIBIB - Diagnostics	500
OD - Support for Testing Development, Research, and Partnerships	1000
TOTAL	26505

Mechanisms for Responding to Future Pandemics

While HHS continues to increase testing capacity for COVID-19 to help facilitate States’ reopening, HHS is also working to strengthen the ability of the Department to respond to future pandemics. These efforts will include the development of a more robust, secure data collection and utilization system; enhancing domestic production and supply chain management capabilities for testing supplies and reagents; and developing robust public-private partnerships that will result in enhanced testing capacity in strategic geographic areas across the U.S. In addition, it will be critical for these programs to evaluate and subsequently implement the most effective methods and infrastructure for reaching underserved and high-risk populations. The Department must also have a streamlined process for identifying a novel pathogen for which a commercial diagnostic test may be needed and supporting the private sector manufacturing and scaling up of production in a timely manner. HHS will use resources provided through the various emergency supplemental appropriations acts to support the efforts described below.

Enhancing Coordination

To support coordination needs for COVID-19 and for the future, HHS will provide strategic oversight, subject matter expertise to States, and logistics and administrative support. This effort is a direct evolution of the Laboratory and Diagnostics Task Force combined with the CBTS Task Force, which successfully implemented testing under the direction of the Assistant Secretary for Health since March 12.

This HHS capacity will support activities related to testing and staff will oversee, implement, and modify as needed the national testing strategy. This effort will enable HHS to provide a robust, sustained capability to execute the objectives and principles of the *Guidelines* and *Testing Blueprint*.

HHS will provide strategic oversight to the operational component of the COVID-19 testing and diagnostic response. HHS will continue to work with manufacturers to bolster inventory, scale promising technologies and invest in demonstration and technical assistance projects. In addition, personnel will act as subject matter experts and as such provide technical assistance to States, territories and tribes to support their testing strategies.

HHS will be staffed with diagnostic subject matter experts, data analysts and epidemiologists, policy advisors, grants management staff, and support staff.

Automated Exchange of Laboratory Data

As testing expansion is being planned and implemented nationwide, aided by substantial Federal support and guidance, it is critical that collection of complete data and automated electronic exchange of those data be included in the planning. This includes defining the critical data elements that must be collected during patient registration and ordering at every testing site, how those data will be collected, and how they will be electronically transmitted to the testing lab; defining required data elements, file formats, and automated transmission methods for having test results reported to the health department; and how all deidentified line level testing data will be reported from the health department to HHS. HHS will provide direct support and technical assistance to testing entities and States in the short term to help ensure all testing data are reported, including point-of-care testing.

Addressing Capacity Needs

Preventing a mismatch between testing capacity and need, and ensuring easily accessible sample collection sites is critical to addressing COVID-19 and any future pandemics. The capacity of laboratories must be identified, which could be done through a registry of laboratory testing capacity. During a pandemic, this registry would also include information on the laboratories receiving test kit shipments. A registry would assist in determining where the testing needs are in order to quickly meet those needs. A registry would also support a network of sample collection sites to identify where individuals can go for testing.

Establishment of regional referral laboratories that maintain a state of readiness to support performing a high volume of diagnostic testing during a pandemic, would also address capacity needs. These regional referral laboratories would be the regional “hub” for performing tests so POC tests can be prioritized for certain areas, like rural and remote areas. These regional referral laboratories would also need to be stocked with testing supplies to address surge capacity needs.

Additionally, a medical and public health laboratory mechanism for working with stakeholders to address resource adequacy is needed. A comparable example would be the North American Electric Reliability Corporation (NERC). Its objective is to meet the electricity needs of end-use customers even when unexpected equipment failures or other factors reduce the amount of available electricity, by ensuring adequacy and security.

Further, building and maintaining laboratory capacity for the future requires providing support to laboratories who have experienced a decrease in an overall volume of testing needs, despite an increase in testing for SARS-CoV-2.

Strategic National Stockpile

For the first time, the Strategic National Stockpile will be stockpiling testing supplies. This step is critical for ensuring States have the supplies needed to address COVID-19 testing needs, and will be necessary for future pandemic preparedness as well.

The table below represents an estimate of the supply volumes needed for 90 days of surge demand, based on an assumption of 12 million tests completed per month (nucleic acid tests only). Cost figures were estimated based on available market data for these products.

Table 4. Strategic National Stockpile Investments

Item	Total Volume Estimate	Unit Cost	Total Cost
Nasal swabs	54,000,000	\$0.18	\$9.5M
Collection/sample tubes	36,000,000	\$1.05	\$37.8M
Transfer media	36,000,000	\$2.69	\$96.8M
Pipettes	36,000,000	\$0.11	\$4.0M
Pipette tips	36,000,000	\$0.06	\$2.3M

Advancing Regulatory Science

The ongoing COVID-19 pandemic highlights several opportunities for regulatory advancement in order to move more swiftly, both now and during future public health emergencies. The EUA pathway and FDA’s guidance and resources have allowed for expedited development, scaled up manufacturing and wide availability of testing. The unprecedented challenges posed by COVID-19 have demonstrated the need for FDA to more clearly identify circumstances in which it may decide not to enforce EUA authorities. Such guidance could facilitate faster implementation of such decisions and, by providing greater clarity to developers and the American public, create a more collaborative atmosphere for public-private partnership. In addition, FDA will try to identify a more streamlined method by which it could add or remove requirements from all applicable EUAs, rather than having to do so one EUA at a time.

Fundamentally, the regulatory architecture that applies to diagnostic testing in the United States serves to ensure patient safety. While the need to expedite regulatory processes remains a

priority, it is implicit that this occur in manner that maintains the quality, reliability and safety of diagnostic testing. Concurrently, given that laboratory quality is dependent upon both the Clinical Laboratory Improvement Amendments (CLIA) and FDA regulatory management of diagnostic devices, it is necessary that FDA, CMS and CDC work collaboratively to advance regulatory science.

Rapidly Engaging Commercial Diagnostic Manufacturers

New diseases and epidemics can emerge without warning and spread quickly. In determining whether the public health laboratory system can meet capacity needs, or whether a high throughput commercial diagnostic may be needed, HHS will consider the likelihood of potential risk of emergence and the potential consequences of the pathogen. Once the threshold has been met for determining a commercial diagnostic may be needed for a pathogen, there are numerous activities that must occur across HHS to support a commercial diagnostic. HHS is planning to further develop a mechanism for identifying when a commercial diagnostic may be needed, and rapidly engaging the commercial sector, including through direct investment from BARDA and NIH.

Conclusion

Testing is a critical component of the national plan to contain COVID-19 and minimize morbidity and mortality, while gradually reopening institutions and commerce within America. With support from the Federal government to ensure States are meeting goals, the State plans for testing will advance the safe reopening of America.

Appendix A

Testing Overview

Testing is and will be the cornerstone of the public health response to SARS-CoV-2. Hence, it is critically important that the national, State, territorial, and tribal testing strategies are robust and flexible to account for the emergence of new technologies and scientific information. This section provides a detailed overview of various technologies and platforms available for both active and passive infection testing. In addition, this section offers use case scenarios for available technologies and platforms. Using this information, States, territories, and tribes can build a robust testing strategy that most effectively utilizes available platforms in their jurisdictions.

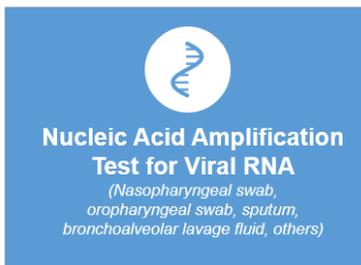
In addition, emerging diagnostic technologies that are currently under development but not yet authorized for use by the FDA are briefly described. States, territories and tribes can utilize the following information as they build out their testing ecosystem and strategies to meet future testing goals.

Assays that are available to test for SARS-CoV-2 can be categorized as either: (1) those that test for active infection or (2) those that help determine prior infection and potential protection. Currently, the real-time reverse transcription-polymerase chain reaction (RT-PCR) is the most common recommended assay for diagnosing COVID-19 cases. Serological tests can play an important role in determining previous infection and in helping to understand the prevalence of individuals in the community who may be immune and protected. Testing for active infection can be performed using laboratory-analyzed tests or POC tests. At this time, testing to determine prior infection can only be performed using laboratory-analyzed tests, however POC tests may be approved for this purpose in the future. Laboratory-analyzed tests must be sent to a laboratory for analysis, a process that takes 1-2 days once received by the lab. Some labs can analyze thousands of tests a day. Results from point-of-care testing may be available at the testing site in less than an hour, although the number of samples that can be processed at once may be smaller than that of laboratory-analyzed tests. These tests are optimal for use in remote, outbreak, and crisis locations.

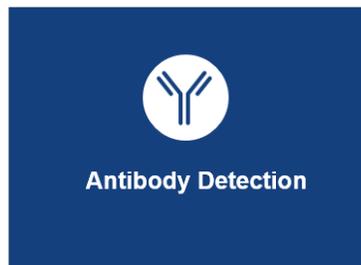
Testing Blueprint – Core Principles

- Every symptomatic patient should receive a timely and accurate diagnostic test.
- To enable early detection, potential community spread should be actively assessed through a strategic approach that identifies asymptomatic individuals who test positive through sentinel monitoring at critical locations, including senior and other congregate living settings and healthcare clinics (particularly those in underserved urban and tribal settings).
- Containment of potential outbreaks, including those uncovered by sentinel monitoring, should be accomplished through systems for contact tracing.
- Testing capacity should be able to be quickly deployed to hot spots, as indicated by monitoring tools such as the Influenza-Like-Illness Surveillance Network (ILI Net) and the National Syndromic Surveillance Program (NSSP) operated by the Centers for Disease Control and Prevention (CDC).
- New technologies, including POC antigen and POC nucleic acid tests, should be leveraged to enhance testing capacity, accuracy, capability, and speed.
- Antibody tests should be used to help assess the number of people in a community who have been previously infected by the virus, especially within critical groups like first responders, essential workers, healthcare providers, and vulnerable populations.
- Data and evidence should drive plan adaptations.

Tests For SARS-CoV-2 and Uses



Current Infection with
SARS-CoV-2



Past exposure to
SARS-CoV-2

The following section describes the types of tests associated with each of these categories (active infection and previous infection), including related technologies and platforms. In addition, the role of each type of test and its use in a comprehensive response to SARS-CoV-2 is discussed. Testing strategies should incorporate each of these types of tests in order to effectively and

efficiently provide testing to different populations across various settings (i.e., LTC residents, healthcare workers, employees in meatpacking plants). Furthermore, utilizing multiple platforms relieves some supply chain constraints by limiting the extent to which states and laboratories are dependent on any one reagent or combination of reagents. To augment such diversification and increase testing capacity, states may consider working within the lab network to loan equipment from labs not performing COVID-19 testing to others that are involved in testing.

Active Infection Testing

Testing with the intent to determine if an individual is currently infected with SARS-CoV-2 is called active infection testing. This type of diagnostic testing detects the presence of SARS-CoV-2 in a clinical specimen and measures the prevalence of individuals with active COVID-19 infection at a given point in time. Active infection testing is the backbone of a comprehensive strategy since understanding the disease prevalence is critical to mitigating further spread. Although RT-PCR is the most widely used method for detection of active infections, other innovative and complementary technologies such as isothermal amplification, antigen detection, and multiplexed-multi-analyte RT-PCRs have been or are currently being developed. These new testing methods will expand the repertoire of tests available for clinicians to diagnose COVID-19.

Nucleic Acid Detection

Both RT-PCR and isothermal techniques rely on amplification of viral genetic material (ribonucleic acid, RNA) to identify SARS-CoV-2. These tests detect the presence of viral genetic material in a clinical sample. A sample is taken from a patient's nose and/or throat using a swab and placed in a solution that breaks open the cells in the sample to separate any viral RNA from other viral material. Any SARS-CoV-2 viral RNA present is amplified by RT-PCR to produce a detectable signal that supports a positive COVID-19 diagnosis.

RT-PCR requires rapid heating and cooling cycles facilitated by sophisticated thermal cycling equipment to amplify target nucleic acids. In contrast, isothermal techniques are designed to amplify nucleic acids at a constant temperature and eliminate the need for a thermal cycler. If SARS-CoV-2 viral RNA is present in the sample, it is quickly amplified to produce a detectable

signal, such as via changing color or fluorescence. Isothermal techniques offer an alternative to traditional RT-PCR assays that could be used to provide reliable test results outside of a laboratory setting, but have not yet been widely adopted. The Abbott ID NOW COVID-19 assay is an example of a diagnostic test that uses an isothermal method to identify SARS-CoV-2.

Beyond RT-PCR and isothermal amplification, there are other amplification methods, such as the proprietary transcription-mediated nucleic acid amplification method employed by the Hologic Panther instrument. Over time, it is expected that other novel methods for nucleic acid amplification will become available, broadening the range of testing technologies available for use.

Authorized tests and testing platforms

The CDC RT-PCR test for SARS-CoV-2 was the first to receive an EUA from the FDA on February 4. Since that time, 82 RT-PCR tests have received an EUA, including lab developed tests. As part of the EUA process, diagnostic tests are authorized for use on specific platforms (instruments). Some higher throughput platforms are compatible with diagnostic tests from multiple manufacturers.

RT-PCR tests that detect SARS-CoV-2 and are compatible with high throughput platforms (defined by CMS as a platform that employs automated processing of more than two hundred specimens a day^{xxxiii}) have been produced by manufacturers such as Abbott, Hologic and Thermo Fisher Scientific. These platforms are most often located in state and local public health laboratories, academic/hospital laboratories, and commercial reference laboratories. Once a sample arrives at the laboratory for analysis, results can be delivered within a few days.

In addition to high throughput tests, the FDA has also authorized rapid POC assays that test for active infection for emergency use. Platforms that run these POC assays include the Abbott ID NOW and Cepheid GeneXpert. Mobile POC platforms (Abbott ID NOW) are small and portable, and are optimal for deployment to rural, outbreak or crisis situations. These POC instruments typically run one sample at a time and provide a result within 5-30 minutes. Larger, multi-chambered POC platforms (Cepheid Gene Xpert) are most often found in hospitals and smaller medical centers. They allow for higher throughput testing than the smaller one-chamber POC platforms (Abbott ID NOW) and typically return results in less than an hour. The components are often self-contained, requiring fewer laboratory resources (i.e., hands-on personnel) than other laboratory-based instruments.

Using a rapid, mobile or facility-based POC platforms to test healthcare providers and symptomatic patients enables maintenance of the workforce (rapid return to work, prevents nosocomial spread, and returns rapid diagnosis for critically ill patients, which also may reduce use of personal protective equipment (PPE) among healthcare personnel treating these patients. In addition, these types of tests are envisioned to supplement laboratory testing, which remains the primary testing mechanism for the nation because of the ability to perform a high volume of tests at one time. However, POC testing is a powerful tool and critical component of the

diagnostic strategy for SARS-CoV-2 (COVID-19) that enables testing to be available for communities and populations that cannot readily access laboratory testing or need to quickly address emerging outbreaks. Recommended uses for POC instruments for COVID-19 diagnostic purposes include:

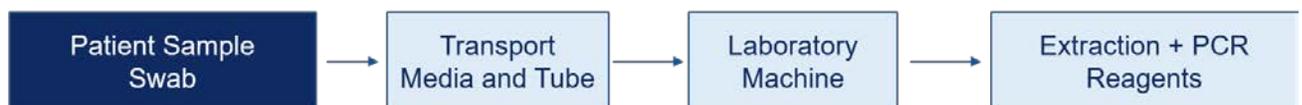
- Deployment to rural hospitals or other critical care sites that lack widely available testing.
- Deployment to long-term care facilities or correctional institutions.
- Rapid deployment to aid in the investigation of a newly identified emerging cluster of cases, such as in response to an outbreak among workers at meatpacking plants.
- Placement in emergency departments for testing of high-priority specimens requiring a rapid result.

There are regulatory considerations that must guide the use of POC instruments for SARS-CoV-2 diagnostic purposes. Testing sites operating a POC diagnostic instrument must have a current certificate via the Clinical Laboratory Improvement Amendments of 1988 (CLIA). During the COVID-19 public health emergency, CMS will permit a Certificate of Waiver laboratory to extend its existing certificate to operate a temporary COVID-19 testing site in an off-site location, such as a long-term care facility.²³ The temporary COVID-19 testing site is only permitted to perform waived tests, consistent with the laboratory's existing certificate and must be under the direction of the existing lab director.

Lab Based and POC Tests

Nucleic acid amplification test for viral RNA

Laboratory Based PCR Test



Point of Care Test

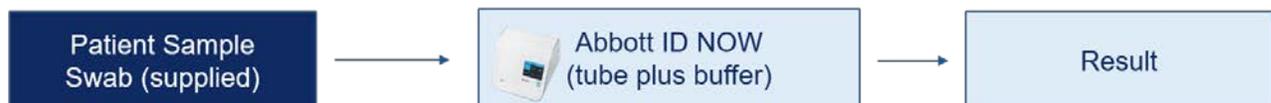


Figure 5. Lab based and POC Tests

Antigen detection

Antigen detection is an alternative approach to identifying the presence of SARS-CoV-2 in a clinical specimen. Rather than identifying viral RNA, an antigen test detects specific proteins that are in the virus. Rapid strep tests are an example of an antigen test. Antigen tests expose a sample taken from a patient to particles that bind to the antigen, indicating the presence of virus. These tests are low complexity, rapid, and function at POC,^{xxxiii,xxxiv} providing increased capacity, capability, and speed to result. The first such test was granted an EUA by the FDA on May 8, with a number of additional candidate COVID-19 antigen tests under development.^{xxxv}

Antigen tests are very specific for the virus, but are not as sensitive as molecular PCR tests. Therefore, positive results from antigen tests are highly accurate, but there is a higher chance of false negatives, so negative results do not rule out infection. With this in mind, negative results from an antigen test may need to be confirmed with a RT-PCR test prior to making treatment decisions or to prevent the possible spread of the virus due to a false negative. Antigen tests may also yield false positives, depending on how the results are displayed. For this reason, it is important that results are interpreted by trained personnel. However, antigen tests are important in the overall response against COVID-19 as they can generally be produced at a lower cost than PCR tests and once multiple manufacturers enter the market, can potentially scale to test millions of Americans per day due to their simpler design, helping our country better identify infection rates closer to real time.

Other Technologies

Multiplexed, multi-analyte diagnostic tests allow for the simultaneous detection of different analytes from a single specimen. For SARS-CoV-2, there are currently several multiplexed, multi-analyte RT-PCR assays capable of detecting and differentiating SARS-CoV-2 from a panel of over 20 respiratory pathogens. These types of assays are critical for ensuring rapid, accurate diagnosis and differentiation of SARS-CoV-2 and influenza patients during influenza and respiratory virus season. The ability to differentiate influenza or other respiratory illnesses from SARS-CoV-2 will allow for appropriate handling of patients, and will become particularly important during flu season in the fall. In addition, because this type of assay provides results for multiple pathogens in one test, it is also reagent sparing. The diagnostician only needs to utilize one set of reagents to get a diagnostic result for multiple pathogens.

Another important addition to the testing toolkit is self-collection and home collection of specimens. The FDA has authorized home specimen collection with return to laboratories by mail. The FDA also allows for self-collection in the presence of clinicians, where the individual being tested uses a nasal swab that they then give to the observing clinician who assures proper handling and transport. These advancements both allow easier access to testing and collection of specimens more distant from healthcare workers to mitigate their risk of exposure to the virus from infected individuals.

Prior Infection

Serology testing—testing for the presence of antibodies in a clinical specimen—are used to determine previous infection from SARS-CoV-2. Serologic tests are usually blood tests that look for antibodies, which are an indicator of an adaptive immune system response to exposure to an infectious agent (pathogen) or foreign protein (antigen). Antibodies are produced over days to weeks after infection. The strength of antibody response depends on several factors, such as age, severity of disease, and overall health status, including conditions that suppress the immune system. Depending on when someone was infected and the timing of the test, the test may not find antibodies in someone with an active COVID-19 infection. Antibodies may not show up for 1 to 3 weeks after onset of illness. Some people may take even longer to develop antibodies, and some people may not develop detectable antibodies.

Unlike the diagnostic tests described above, which are used to confirm the presence of the pathogen, antibody tests help determine whether someone was previously infected—even if that person never showed symptoms. However, the presence of antibodies does not necessarily indicate immunity (resistance to infection). Additionally, while serological testing cannot be used for confirmatory diagnosis, a positive antibody result could indicate a recent infection and does not mean that a person is no longer shedding virus or is no longer infectious.

Serologic tests detect different types of antibodies, most commonly IgM and IgG. IgM is one of the first types of antibodies produced after a pathogen has entered the body and is most useful for determining recent infection. In most infections, IgG generally develops after IgM, and may remain detectable for months or years. Although the kinetics of antibody response to COVID-19 are not yet fully understood, a positive result from appropriately validated serologic tests that are designed to be very specific to the SARS-CoV-2 virus can confirm that a patient has been infected by SARS-CoV-2. While serology tests are not used for diagnosis, they play an important role in determining previous infection and in helping to understand the prevalence of individuals in the community who may be immune and protected.

Additionally, serology tests can be useful to examine demographics and geographic patterns to determine which communities may have experienced a higher case rate, and therefore may have higher rates of ‘herd immunity.’ Likewise, serological surveillance can be utilized to monitor viral transmission rates and emergence in communities, and serological test results may also aid in determining who may qualify to donate blood that can be used to manufacture convalescent plasma as a possible treatment for those who are seriously ill from COVID-19.

The core principles of the *Testing Blueprint* include the use of antibody tests, citing their value in assessing the number of people in a community previously infected with SARS-CoV-2, particularly within critical groups such as first responders, essential workers, healthcare providers, and vulnerable populations. Antibody testing is also identified as a component of the proposed state or regional gating criteria, including in the Guidelines for Opening Up America Again. Specifically, this type of testing is cited as a part of the requisite, robust testing program necessary for at-risk healthcare workers.

Serology

Antibody detection

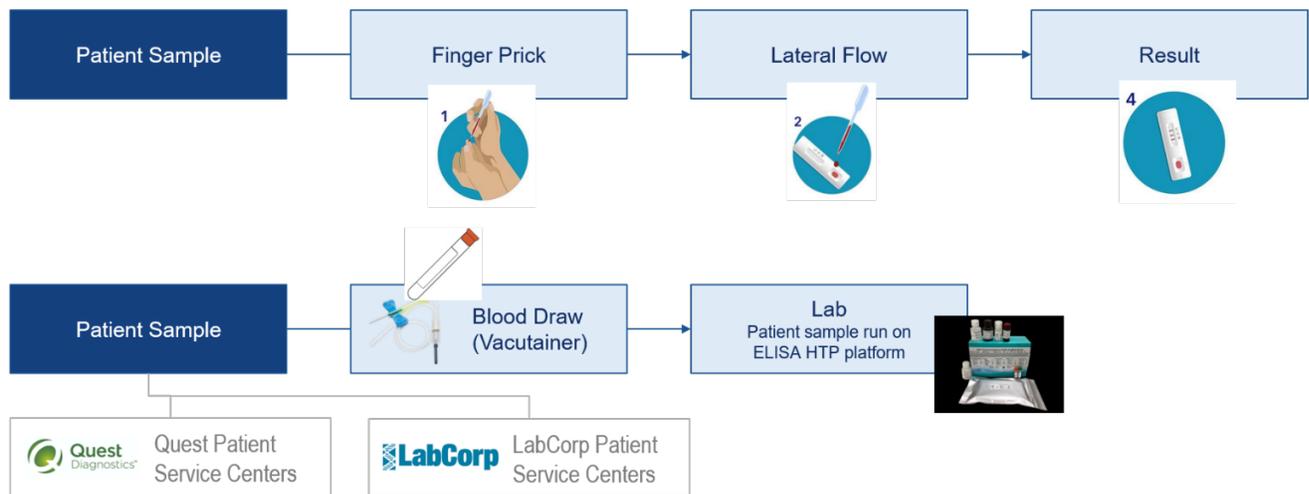


Figure 6. Serology test process

Authorized Tests

Laboratory serologic assays have received FDA emergency use authorization. Serologic testing technologies include single-use, low-throughput lateral flow tests where the presence of antibody is demonstrated by a color change on a paper strip, and laboratory-based immunoassays which allow for processing of many samples at the same time. A number of laboratory-based serological assays have received EUAs from the FDA, including tests manufactured by Abbott, Ortho, and DiaSorin. Individual labs including Wadsworth New York and Mount Sinai Hospital have also developed their own serological tests for use within their laboratory systems (laboratory developed tests, LDT), but which are not available on the commercial market. Currently, there are no FDA-authorized COVID-19 serologic POC tests, although several are in development.

Long-term Immunity

At present, it is unclear whether the development of antibodies resulting from SARS-CoV-2 infection will provide an individual with protection from a future infection. Early studies using animal models suggest that this may be the case;^{xxxvi} however, this remains an area of active investigation. Representatives from BARDA, CDC, FDA, NIH, OASH, DoD, and White House Office of Science and Technology Policy (OSTP) are working with members of academia and the medical community to determine whether positive serologic tests are indicative of protective immunity against SARS-CoV-2. This work includes assessing the level of antibodies required for protection, the duration of that protection, and the factors associated with whether a person

develops a protective antibody response. Answers to these questions will be critical to informing state-level diagnostic plans, as well as the national strategy for testing.

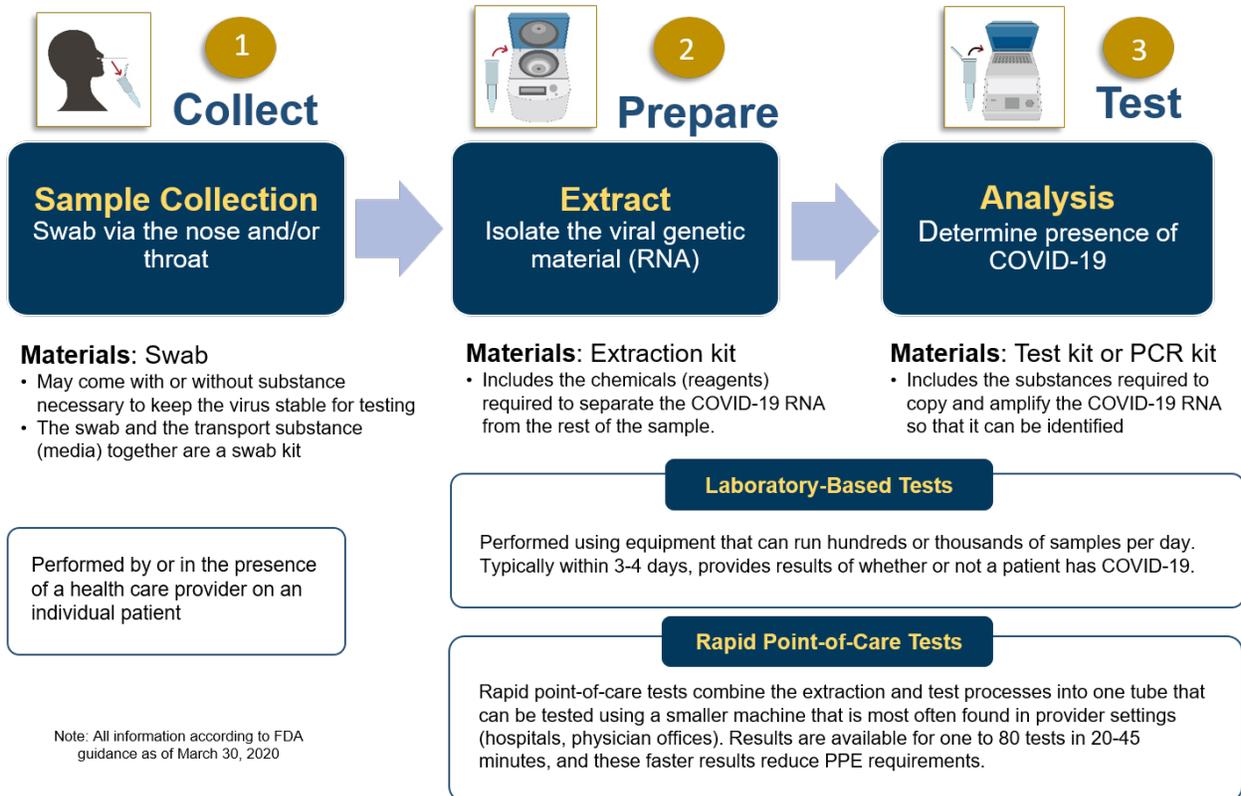
Test Performance Criteria and Fitness for Purpose

Test performance is critical for determining the fitness of an assay for a specific purpose, whether that be in diagnosing an active infection or identifying prior infection. Common performance metrics include a test's sensitivity, which is the likelihood of a positive test result among those with disease, and specificity, which is the likelihood of a negative test among those without the disease. These measures vary among tests and test types and in certain circumstances; there are rationales to include tests that favor one characteristic over another. For example, diagnostic tests used to detect virus to rule-in or rule-out disease should have higher specificity (weighted toward defining true negatives) to avoid allowing COVID-19 positive patients back into the general population. Alternatively, screening tests, which are typically used to screen large numbers of asymptomatic individuals who are at risk for disease, are weighted toward high sensitivity so as not to miss samples that are potentially positive.

Tests are also described by their positive and negative predictive values (PPV and NPV). These measures are calculated using a test's sensitivity, specificity, and an assumed percentage of individuals in the population who are positive for SARS-CoV-2 (which is called "prevalence" in these calculations). Every test returns some false positive and false negative results. The PPV and NPV help those who are interpreting viral detection tests understand, given how prevalence of disease in a community, how likely it is that a person who receives a positive result from a test truly is positive for SARS-CoV-2 and how likely it is that a person who receives a negative result from a test is truly negative for SARS-CoV-2. The PPV and NPV of a test depend heavily on the prevalence of what that test is intended to detect.

Appendix B

Testing Process



Appendix C

Nursing Home Reopening Recommendations



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-30-NH

DATE: May 18, 2020

TO: State Officials

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Nursing Home Reopening Recommendations for State and Local Officials

Memorandum Summary

- CMS is committed to taking critical steps to ensure America's nursing homes are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- **Recommendations for State and Local Officials:** CMS is providing recommendations to help determine the level of mitigation needed to prevent the transmission of COVID-19 in nursing homes. The recommendations cover the following items:
 - **Criteria for relaxing certain restrictions and mitigating the risk of resurgence:** Factors to inform decisions for relaxing nursing home restrictions through a phased approach.
 - **Visitation and Service Considerations:** Considerations allowing visitation and services in each phase.
 - **Restoration of Survey Activities:** Recommendations for restarting certain surveys in each phase.

Background

Nursing homes have been severely impacted by COVID-19, with outbreaks causing high rates of infection, morbidity, and mortality. The vulnerable nature of the nursing home population combined with the inherent risks of congregate living in a healthcare setting, requires aggressive efforts to limit COVID-19 exposure and to prevent the spread of COVID-19 within nursing homes.

Recommendations for States

This memorandum provides recommendations for State and local officials to help them determine the level of mitigation needed for their communities' Medicare/Medicaid certified long term care facilities (hereinafter, 'nursing homes') to prevent the transmission of COVID-19. We encourage State leaders to collaborate with the state survey agency, and State and local health departments to decide how these and other criteria or actions should be implemented in their state. Examples of how a State may choose to implement these recommendations include:

- A State requiring all facilities to go through each phase at the same time (i.e., waiting until all facilities have met entrance criteria for a given phase).
- A State allowing facilities in a certain region (e.g., counties) within a state to enter each phase at the same time.
- A State permitting individual nursing homes to move through the phases based on each nursing home’s status for meeting the criteria for entering a phase.

Given the critical importance in limiting COVID-19 exposure in nursing homes, decisions on relaxing restrictions should be made with careful review of a number of facility-level, community, and State factors/orders, and in collaboration with State and/or local health officials and nursing homes. Because the pandemic is affecting communities in different ways, State and local leaders should regularly monitor the factors for reopening and adjust their plans accordingly. Factors that should inform decisions about relaxing restrictions in nursing homes include:

- **Case status in community:** State-based criteria to determine the level of community transmission and guides progression from one phase to another. For example, a decline in the number of new cases, hospitalizations, or deaths (with exceptions for temporary outliers).
- **Case status in the nursing home(s):** Absence of any new nursing home onset¹ of COVID-19 cases (resident or staff), such as a resident acquiring COVID-19 in the nursing home.
- **Adequate staffing:** No staffing shortages and the facility is not under a contingency staffing plan.
- **Access to adequate testing:** The facility should have a testing plan in place based on contingencies informed by the Centers for Disease Control and Prevention (CDC). At minimum, the plan should consider the following components:
 - The capacity for **all** nursing home **residents** to receive a single baseline COVID-19 test. Similarly, the capacity for all residents to be tested upon identification of an individual with symptoms consistent with COVID-19, or if a staff member tests positive for COVID-19. Capacity for continuance of weekly re-testing of all nursing home residents until all residents test negative;
 - The capacity for **all** nursing home **staff** (including volunteers and vendors who are in the facility on a weekly basis) to receive a single baseline COVID-19 test, with re-testing of all staff continuing every week (note: State and local leaders may adjust the requirement for weekly testing of staff based on data about the circulation of the virus in their community);
 - Written screening protocols for all staff (each shift), each resident (daily), and all persons entering the facility, such as vendors, volunteers, and visitors;
 - An arrangement with laboratories to process tests. The test used should be able to detect SARS-CoV-2 virus (e.g., polymerase chain reaction (PCR)) with greater than 95% sensitivity, greater than 90% specificity, with results obtained rapidly

¹ A “new, nursing home onset” refers to COVID-19 cases that originated in the nursing home, and not cases where the nursing home admitted individuals from a hospital with a known COVID-19 positive status, or unknown COVID-19 status but became COVID-19 positive within 14 days after admission. In other words, if the number of COVID-19 cases increases because a facility is admitting residents from the hospital AND they are practicing effective Transmission-Based Precautions to prevent the transmission of COVID-19 to other residents, that facility may still advance through the phases of reopening. However, if a resident contracts COVID-19 within the nursing home without a prior hospitalization within the last 14 days, this facility should go back to the highest level of mitigation, and start the phases over.

(e.g., within 48 hours). Antibody test results should not be used to diagnose someone with an active SARS-CoV-2 infection.

- A procedure for addressing residents or staff that decline or are unable to be tested (e.g., symptomatic resident refusing testing in a facility with positive COVID-19 cases should be treated as positive).
- **Universal source control:** Residents and visitors wear a cloth face covering or facemask. If a visitor is unable or unwilling to maintain these precautions (such as young children), consider restricting their ability to enter the facility. All visitors should maintain social distancing and perform hand washing or sanitizing upon entry to the facility.
- **Access to adequate Personal Protective Equipment (PPE) for staff:** Contingency capacity strategy is allowable, such as [CDC's guidance at Strategies to Optimize the Supply of PPE and Equipment](#) (facilities' crisis capacity PPE strategy would not constitute adequate access to PPE). All staff wear all appropriate PPE when indicated. Staff wear cloth face covering if facemask is not indicated, such as administrative staff.
- **Local hospital capacity:** Ability for the local hospital to accept transfers from nursing homes.

Contact: For questions or concerns regarding this memo, please contact DNH_TriageTeam@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Branch training coordinators immediately.

/s/

David R. Wright

Attachments:

Recommended Nursing Home Phased Re-opening for States

cc: Survey & Operations Group (SOG) Management

Attachment 1 – Recommended Nursing Home Phased Reopening for States

The reopening phases below cross-walk to the phases of the plan for [Opening Up America Again](#), and includes efforts to maintain rigorous infection prevention and control, as well as resident social engagements and quality of life. Note: The Opening Up America Guidance for communities includes visitation guidance for “senior care facilities.” The term “senior care facilities” refers to a broader set of facilities that may be utilized by seniors, and is not specific to Medicare/Medicare certified long term care facilities (i.e., nursing homes), whereas, this guidance is specific to nursing homes.

Due to the elevated risk COVID-19 poses to nursing home residents, we recommend additional criteria for advancing through phases of reopening nursing homes than is recommended in the broader Administration’s Opening Up America Again framework. For example:

- Nursing homes should not advance through any phases of reopening or relax any restrictions until all residents and staff have received a base-line test, and the appropriate actions are taken based on the results;
- States should survey those nursing homes that experienced a significant COVID-19 outbreak prior to reopening to ensure the facility is adequately preventing transmission of COVID=19; and
- Nursing homes should remain in the current state of highest mitigation while the community is in Phase 1 of Opening Up America Again (in other words, a nursing home’s reopening should lag behind the general community’s reopening by 14 days).

For additional criteria, please see the Appendix.

Status	Criteria for Implementation	Visitation and Service Considerations	Surveys that will be performed at each phase
Current state: Significant Mitigation and Phase 1 of Opening Up America Again	<ul style="list-style-type: none"> • Most facilities are in a posture that can be described as their highest level of vigilance, regardless of transmission within their communities. 	<ul style="list-style-type: none"> • Visitation generally prohibited, except for compassionate care situations. In those limited situations, visitors are screened and additional precautions are taken, including social distancing, and hand hygiene (e.g., use alcohol-based hand rub upon entry). All visitors must wear a cloth face covering or facemask for the duration of their visit. • Restricted entry of non-essential healthcare personnel. • Communal dining limited (for COVID-19 negative or asymptomatic residents only), but residents may eat in the same room with social distancing (limited number of people at tables and spaced by at least 6 feet). • Non-medically necessary trips outside the building should be avoided. 	<ul style="list-style-type: none"> • Investigation of complaints alleging there is an immediate serious threat to the resident’s health and safety (known as Immediate Jeopardy) • Revisit surveys to confirm the facility has removed any Immediate Jeopardy findings • Focused infection control surveys • Initial survey to certify that the provider has met the required conditions to participate in the Medicare Program (initial certification surveys)

Status	Criteria for Implementation	Visitation and Service Considerations	Surveys that will be performed at each phase
		<ul style="list-style-type: none"> • Restrict group activities, but some activities may be conducted (for COVID-19 negative or asymptomatic residents only) with social distancing, hand hygiene, and use of a cloth face covering or facemask. • For medically necessary trips away from of the facility: <ul style="list-style-type: none"> ○ The resident must wear a cloth face covering or facemask; and ○ The facility must share the resident’s COVID-19 status with the transportation service and entity with whom the resident has the appointment. • 100% screening of all persons entering the facility and all staff at the beginning of each shift: <ul style="list-style-type: none"> ○ Temperature checks ○ Ensure all outside persons entering building have cloth face covering or facemask. ○ Questionnaire about symptoms and potential exposure ○ Observation of any signs or symptoms • 100% screening for all residents: <ul style="list-style-type: none"> ○ Temperature checks ○ Questions about and observation for other signs or symptoms of COVID-19 (at least daily) • Universal source control for everyone in the facility. Residents and visitors entering for compassionate care wear cloth face covering or facemask. • All staff wear appropriate PPE when they are interacting with residents, to the extent PPE is available and consistent with CDC guidance on optimization of PPE. Staff wear cloth face covering if facemask is not indicated. • All staff are tested weekly. All residents are tested upon identification of an individual with symptoms consistent with COVID-19 or if staff have tested positive for COVID-19. Weekly testing continues until all residents test negative. • Dedicated space in facility for cohorting and managing care for residents with COVID-19; plan to 	<ul style="list-style-type: none"> • Any State-based priorities (e.g., localized “hot spots,” “strike” teams, etc.)

Status	Criteria for Implementation	Visitation and Service Considerations	Surveys that will be performed at each phase
Phase 2 of Reopening nursing homes and Opening Up America Again	<ul style="list-style-type: none"> • Case status in community has met the criteria for entry into phase 2 (no rebound in cases after 14 days in phase 1). • There have been no new, nursing home onset COVID cases in the nursing home for 14 days. • The nursing home is not experiencing staff shortages. • The nursing home has adequate supplies of personal protective equipment and essential cleaning and disinfection supplies to care for residents. • The nursing home has adequate access to testing for COVID-19. • Referral hospital(s) have bed capacity on wards and intensive care units. 	<p>manage new/readmissions with an unknown COVID-19 status and residents who develop symptoms.</p> <ul style="list-style-type: none"> • Visitation generally prohibited, except for compassionate care situations. In those limited situations, visitors are screened and additional precautions are taken, including social distancing, and hand hygiene (e.g., use alcohol-based hand rub upon entry). All visitors must wear a cloth face covering or facemask for the duration of their visit. • Allow entry of limited numbers of non-essential healthcare personnel/contractors as determined necessary by the facility, with screening and additional precautions including social distancing, hand hygiene, and cloth face covering or facemask. • Communal dining limited (for COVID-19 negative or asymptomatic residents only), but residents may eat in the same room with social distancing (limited number of people at tables and spaced by at least 6 feet). • Group activities, including outings, limited (for asymptomatic or COVID-19 negative residents only) with no more than 10 people and social distancing among residents, appropriate hand hygiene, and use of a cloth face covering or facemask. • For medically necessary trips outside of the facility: <ul style="list-style-type: none"> ○ The resident must wear a cloth face covering or facemask; and ○ The facility must share the resident’s COVID-19 status with the transportation service and entity with whom the resident has the appointment. • 100% screening of all persons entering the facility and all staff at the beginning of each shift: <ul style="list-style-type: none"> ○ Temperature checks ○ Ensure all outside persons entering building have cloth face covering or facemask. ○ Questionnaire about symptoms and potential exposure ○ Observation of any signs or symptoms • 100% screening (at least daily) for all residents 	<ul style="list-style-type: none"> • Investigation of complaints alleging either Immediate Jeopardy or actual harm to residents • Revisit surveys to confirm the facility has removed any Immediate Jeopardy findings • Focused infection control surveys • Initial certification surveys • State-based priorities (e.g., localized “hot spots,” “strike” teams, etc.) • See Appendix for recommendations for prioritizing facilities to be surveyed

Status	Criteria for Implementation	Visitation and Service Considerations	Surveys that will be performed at each phase
		<ul style="list-style-type: none"> ○ Temperature checks ○ Questions about and observation for other signs or symptoms of COVID-19 ● Universal source control for everyone in the facility. Residents and visitors entering for compassionate care wear cloth face covering or facemask. ● All staff wear all appropriate PPE when indicated. Staff wear cloth face covering if facemask is not indicated, such as administrative staff. ● Test all staff weekly. Test all residents upon identification of an individual with symptoms consistent with COVID-19, or if staff have tested positive for COVID-19. Weekly testing continues until all residents test negative. ● Dedicated space in facility for cohorting and managing care for residents with COVID-19; plan to manage new/readmissions with an unknown COVID-19 status and residents who develop symptoms. 	
Phase 3 of Reopening nursing homes and Opening Up America Again	<ul style="list-style-type: none"> ● Community case status meets criteria for entry to phase 3 (no rebound in cases during phase 2). ● There have been no new, nursing home onset COVID cases in the nursing home for 28 days (through phases 1 and 2). ● The nursing home is not experiencing staff shortages. ● The nursing home has adequate supplies of personal protective equipment and essential cleaning and disinfection supplies to care for residents. ● The nursing home has adequate access to testing for COVID-19. 	<ul style="list-style-type: none"> ● Visitation allowed with screening and additional precautions including ensuring social distancing and hand hygiene (e.g., use alcohol-based hand rub upon entry). All visitors must wear a cloth face covering or facemask for the duration of their visit. ● Allow entry of non-essential healthcare personnel/contractors as determined necessary by the facility, with screening and additional precautions including social distancing, hand hygiene, and cloth face covering or facemask. ● Communal dining limited (for COVID-19 negative or asymptomatic residents only), but residents may eat in the same room with social distancing (limited number of people at tables and spaced by at least 6 feet). ● Group activities, including outings, allowed (for asymptomatic or COVID-19 negative residents only) with no more than the number of people where social distancing among residents can be maintained, appropriate hand hygiene, and use of a cloth face covering or facemask. 	<ul style="list-style-type: none"> ● Normal Survey operations ● All complaint and revisit surveys required to identify and resolve any non-compliance with health and safety requirements ● Standard (recertification) surveys and revisits ● Focused infection control surveys ● State-based priorities (e.g., localized “hot spots,” “strike” teams, etc. ● See Appendix for recommendations for prioritizing facilities to be surveyed

Status	Criteria for Implementation	Visitation and Service Considerations	Surveys that will be performed at each phase
	<ul style="list-style-type: none"> • Referral hospital(s) have bed capacity on wards and intensive care units. 	<ul style="list-style-type: none"> • Allow entry of volunteers, with screening and additional precautions including social distancing, hand hygiene, and cloth face covering or facemask. • For medically necessary trips outside of the facility: <ul style="list-style-type: none"> ○ The resident must wear a mask; and ○ The facility must share the resident's COVID-19 status with the transportation service and entity with whom the resident has the appointment. • 100% screening of all persons entering the facility and all staff at the beginning of each shift: <ul style="list-style-type: none"> ○ Temperature checks. ○ Ensure all outside persons entering building have cloth face covering or facemask. ○ Questionnaire about symptoms and potential exposure ○ Observation of any signs or symptoms • 100% screening (at least daily) for all residents <ul style="list-style-type: none"> ○ Temperature checks ○ Questions about and observation for other signs or symptoms of COVID-19 • Universal source control for everyone in the facility. Residents and visitors wear cloth face covering or facemask. • All staff wear all appropriate PPE when indicated. Staff wear cloth face covering if facemask is not indicated, such as administrative staff. • Test all staff weekly. Test all residents upon identification of an individual with symptoms consistent with COVID-19, or if staff have tested positive for COVID-19. Weekly testing continues until all residents test negative. • Dedicated space in facility for cohorting and managing care for residents with COVID-19; plan to manage new/readmissions with an unknown COVID-19 status and residents who develop symptoms. 	

APPENDIX

Additional Recommendations

- Reminder: When a community enters phase 1 of Opening Up America Again, nursing homes remain at their highest level of vigilance and mitigation (e.g., visitation restricted except in compassionate care situations). Nursing homes do not begin to de-escalate or relax restrictions until their surrounding community satisfies gating criteria and enters phase 2 of Opening Up America Again.
- A nursing home should spend a minimum of 14 days in a given phase, with no new nursing home onset of COVID-19 cases, prior to advancing to the next phase.
- A nursing home may be in different phases than its surrounding community based on the status of COVID-19 inside the facility, and the availability of key elements including, but not limited to PPE², testing, and staffing. For example, if a facility identifies a new, nursing home onset COVID-19 case in the facility while in **any** phase, that facility goes back to the **highest** level of mitigation, and starts over (even if the community is in phase 3).
- States may choose to have a longer waiting period (e.g., 28 days) before relaxing restrictions for facilities that have had a significant outbreak of COVID-19 cases, facilities with a history of noncompliance with infection control requirements, facilities with issues maintaining adequate staffing levels, or any other situations the state believes may warrant additional oversight or duration before being permitted to relax restrictions.

State Survey Prioritization (Starting in Phase 2 of the above chart)

States should use the following prioritization criteria within each phase when determining which facilities to begin to survey first.

- For investigating complaints (and Facility-Reported Incidents (FRIs), facilities with reports or allegations of:
 1. Abuse or neglect
 2. Infection control, including lack of notifying families and their representatives of COVID-19 information (per new requirements at 42 CFR 483.80(g)(3))
 3. Violations of transfer or discharge requirements
 4. Insufficient staffing or competency
 5. Other quality of care issues (e.g., falls, pressure ulcers, etc.)

In addition, a State agency may take other factors into consideration in its prioritization decision. For example, the State may identify a trend in allegations that indicates an increased risk of harm to residents, or the State may receive corroborating information from other sources regarding the allegation. In this case, the State may prioritize a facility for a survey higher than a facility that has met the above criteria.
- For standard recertification surveys:
 1. Facilities that have had a significant number of COVID-19 positive cases
 2. Special Focus Facilities
 3. Special Focus Facility candidates

² Facilities should review the Centers for Disease Control and Prevention's [guidance on COVID-19 for healthcare professionals](#).

4. Facilities that are overdue for a standard survey (> 15 months since last standard survey) and a history of noncompliance at the harm level (citations of "G" or above) with the below items:
 - Abuse or neglect
 - Infection control
 - Violations of transfer or discharge requirements
 - Insufficient staffing or competency
 - Other quality of care issues (e.g., falls, pressure ulcers, etc.)

For example, a facility whose last standard survey was 24 months ago and was cited for abuse at a "G" level of noncompliance, would be surveyed earlier (i.e., prioritized higher) than a facility whose last standard survey was 23 months ago and had lower level deficiencies. We recognize that there are many different scenarios or combinations of timing of surveys and types of noncompliance that will exist. We defer to States for final decisions on scheduling surveys consistent with CMS survey prioritization guidelines.

Nursing Home Reopening Recommendations Frequently Asked Questions

This FAQ answers a range of questions on the topics of:

- Reopening
- Visitation
- Testing Requirements

1. Where can I find the most up-to-date information from CMS on COVID-19?

For a complete and updated list of CMS actions in response to COVID-19, and other information specific to CMS, please visit the [Current Emergencies Website](#). To keep up with the important work the White House Task Force is doing in response to COVID-19, visit www.coronavirus.gov.

2. What is CMS releasing today?

CMS is providing recommendations to state and local officials to help determine the level of mitigation required to continue preventing the spread of COVID-19 within nursing homes, especially as many states begin a phased reopening.

3. What steps should nursing homes take before reopening to visitors?

Nursing homes should continue to follow CMS and CDC guidance for preventing the transmission of COVID-19. In addition, they should follow state and local direction. Because nursing home residents are especially vulnerable, CMS does not recommend opening facilities to visitors (except for compassionate care situations) until phase three when:

- there have been no new, nursing home onset COVID-19 cases in the nursing home for 28 days (through phases one and two)
- the nursing home is not experiencing staff shortages
- the nursing home has adequate supplies of personal protective equipment and essential cleaning and disinfection supplies to care for residents
- the nursing home has adequate access to testing for COVID-19
- Referral hospital(s) have bed capacity on wards and intensive care units

4. Why are there additional criteria for reopening nursing homes when many states seem to be loosening restrictions on workplaces, business, stores, etc.

Nursing homes have been severely impacted by COVID-19, with outbreaks causing high rates of infection, morbidity, and mortality. The vulnerable nature of the nursing home population combined with the inherent risks of close quarter living in a healthcare

setting, requires aggressive efforts to limit COVID-19 exposure and to prevent the spread of COVID-19 within nursing homes. Continued adherence to these criteria will help to ensure residents remain safe.

5. Why isn't CMS requiring testing in nursing homes?

The Guidelines for Opening Up America Again call for robust testing and contact tracing. Nursing home testing is a cornerstone of these guidelines and efforts. The guidelines direct states to be prepared to deploy testing resources first and foremost to nursing homes so that any potential outbreak of the coronavirus among the most vulnerable population can be monitored. Testing should be done proactively in nursing homes and everyone should be tested – this is the backbone of building a national coronavirus surveillance system.

To aid in this effort and rapidly expand COVID-19 testing, CMS recently issued a [ruling](#) that Medicare will pay a rate of \$100 for certain laboratory tests that use high-throughput technologies to rapidly process large numbers of specimens for COVID-19 testing per day. On April 2, CMS issued a call to action for nursing homes and state and local governments urging leaders to work closely with nursing homes on access to testing and PPE.

CMS is constantly evaluating our guidance and the status of the conditions in facilities. We will continue to make changes based on those evaluations, as we have issued an unprecedented amount of guidance to date.

6. What is CMS doing to increase testing in nursing homes?

In the Guidelines for [Opening Up America Again](#), testing is one of the Core State Preparedness Responsibilities. Specifically, nursing home testing is a cornerstone of these guidelines and efforts. The guidelines direct states to be prepared to deploy testing resources first and foremost to nursing homes to enable close monitoring of any potential outbreak of Coronavirus among this vulnerable population. Additionally, the CMS issued a call to action for state and local governments that reinforced its infection control responsibilities and urged leaders to determine the local needs for COVID-19 testing, including making testing in nursing homes a priority.

Testing should be done proactively in nursing homes and everyone should be tested – this is the backbone of building a national coronavirus surveillance system. To aid in this effort and rapidly expand COVID-19 testing, CMS recently issued a [ruling](#) that Medicare will pay a rate of \$100 for certain laboratory tests that use high-throughput technologies to rapidly process large numbers of specimens for COVID-19 testing per day. In addition to

expanding access to diagnostic testing available to Medicare beneficiaries, CMS expedited review of applications for a Clinical Laboratory Improvement Amendments (CLIA) certificate and ensuring that laboratories located in the United States wishing to perform COVID-19 testing are able to begin testing as quickly as possible. In early April, CMS also implemented a change to Medicare payment policies that allows for payment to independent laboratories for specimen collection from beneficiaries who are homebound or non-hospital inpatients for COVID-19 testing under certain circumstances.

7. Is COVID-19 testing required in nursing homes, or do nursing homes have to comply with family requests for testing of residents?

CMS and our partners on the White House Coronavirus Task Force are taking aggressive action to protect those most vulnerable to the 2019 Novel Coronavirus (COVID-19). A dedicated Nursing Home Task Force, which includes CMS and the Centers for Disease Control and Prevention (CDC), meets daily with a singular focus of safeguarding the health of the elderly residing in nursing homes.

A decision to order a COVID-19 test for a patient is made by that patient’s physician or health care provider. CMS continues to direct nursing homes to the latest guidance from the CDC on COVID-19 testing. In addition, nursing homes must follow any state or local requirements for COVID-19 screening, testing, and reporting. Ultimately, nursing homes are responsible for the health and safety of their residents.

CMS has taken several important actions to expand access to diagnostic testing available to Medicare beneficiaries, individuals, nursing homes and hospitals during this public health emergency. Last month, CMS expedited review of applications for a CLIA certificate and ensuring that laboratories located in the United States wishing to perform COVID-19 testing are able to begin testing as quickly as possible. In addition, in early April, CMS implemented a change to Medicare payment policies that allows for payment to independent laboratories for specimen collection from beneficiaries who are homebound or non-hospital inpatients for COVID-19 testing under certain circumstances. For a full list of actions, visit CMS’ [Frequently Asked Questions \(FAQs\) document](#).

8. What factors should state and local health officials consider before relaxing restrictions in nursing homes?

CMS encourages any decisions to relax requirements within nursing homes to be made after a careful review of facility-level, community, and state factors/orders as well as in collaboration with state and local health officials and nursing homes. Additionally, state and local officials should consider the following as a part of a comprehensive reopening plan:

- Case status in surrounding community
- Case status in the nursing home(s)
- Staffing levels
- Access to adequate testing for residents and staff
- Personal Protective Equipment supplies
- Local hospital capacity

More information can be found in the Nursing Home Reopening Recommendations Memo (insert URL)

9. How often should a nursing home test its staff?

All staff should receive a baseline test, and continue to be tested weekly.

10. How often should a nursing home test its residents?

Nursing homes should have a comprehensive plan for testing. All residents should receive a single baseline test for COVID-19. Also, all residents should be tested upon identification of an individual with symptoms consistent with COVID-19 or if an employee or staff member tested positive for COVID-19.

11. When will visitors be allowed in nursing homes?

Continuing to restrict visitation is understandably challenging for families, but is necessary in order to protect residents from possible transmission of the virus. Nursing homes should continue to restrict visitation in general based upon the following recommended guidelines:

Phase One: Visitation is generally prohibited, except for compassionate care situations. In those limited situations, visitors are screened and additional precautions are taken,

including social distancing, and hand hygiene (e.g., use alcohol-based hand rub upon entry). All visitors wear a cloth face covering or facemask for the duration of their visit.

Phase Two: Due to the elevated risk COVID-19 poses to the health of nursing home residents, visitation is still generally prohibited, except for compassionate care situations. In those limited situations, visitors are screened and additional precautions are taken, including social distancing, and hand hygiene (e.g., use alcohol-based hand rub upon entry). All visitors wear a cloth face covering or facemask for the duration of their visit.

Phase Three: Visitation allowed with screening and additional precautions including ensuring social distancing and hand hygiene (e.g., use alcohol-based hand rub upon entry). All visitors must a cloth face covering or facemask for the duration of their visit.

Appendix D

ELC Health Care Enhancement: 2020 Supplement Guidance to the States



ELC ENHANCING DETECTION

Emerging Issues (E) Project: Funding for the Enhanced
Detection, Response, Surveillance, and Prevention of COVID-19
Supported through the Paycheck Protection Program and Health
Care Enhancement Act of 2020

CONTENTS

Background and purpose1

Funding strategy2

Process for workplan and budget submission3

Activities.....5

Performance measures and reporting9

**ELC ENHANCING DETECTION
EMERGING ISSUES (E) PROJECT**

BACKGROUND AND PURPOSE

Over the past 25 years, the Centers for Disease Control and Prevention’s (CDC) Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) cooperative agreement has enhanced the capacity of each of our recipient jurisdictions’ public health capacity to cohesively and comprehensively address infectious disease needs. In addition to foundational support for epidemiology, laboratory, and health information systems, the ELC also supports disease-specific program areas (e.g., respiratory diseases; healthcare associated infections). The portfolio of ELC-supported activities at each jurisdiction is overseen by an ELC Governance Team with representation from epidemiology, laboratory, and health information systems. This structure has been successfully utilized by ELC recipients to manage activities and funding from special appropriations provided in response to a number of infectious disease emergencies (e.g., H1N1, Ebola, and Zika).

As part of the “Paycheck Protection Program and Health Care Enhancement Act of 2020 (P.L. 116-139, Title I)”, the ELC is awarding a total of \$10.25 billion dollars to our recipient base in a program-initiated component funding under the Emerging Issues (E) Project of CK19-1904, henceforth, “ELC Enhancing Detection” supplement. These funds are broadly intended to provide critical resources to state, local, and territorial health departments in support of a broad range of COVID-19/SARS-CoV-2 testing and epidemiologic surveillance related activities. Direct recipients are limited to existing jurisdictions covered under CK19-1904¹. These resources should complement, not duplicate, existing funding provided to jurisdictions, including the ELC Community-based Surveillance and ELC CARES Act supplements. Additionally, recipients should leverage and build upon existing ELC infrastructure that emphasizes the coordination and critical integration of laboratory with epidemiology and health information systems in order to maximize the public health impact of available resources. Ongoing monitoring of milestones and performance measures will be utilized to gauge progress toward successful completion of priority activities supported with these funds.

Resources provided via this award mechanism should support necessary expenses to implement and oversee expanded testing capacity for COVID-19/SARS-CoV-2, including the ability to process, manage, analyze, use, and report the increased data produced. Recipients will establish a robust SARS-CoV-2 testing program that ensures adequate testing is made available according to CDC priorities, including but not limited to: diagnostic tests, tests

¹ Only current ELC recipients are eligible to receive awards associated with the supplement described in this guidance. While tribal nations are not included in these awards, other federal support is provided in the *Paycheck Protection Program and Health Care Enhancement Act of 2020*.

for contact tracing, and surveillance of asymptomatic persons to determine community spread. Recipients should assure that provisions are in place to meet future surge capacity testing needs including point of care or other rapid result testing for local outbreaks. Plans should include plans for testing at non-traditional sites (e.g., retail sites, community centers, residential medical facilities, or pharmacies); testing of at risk populations including elderly, disabled, those in congregate living facilities including prisons, racial and ethnic minorities, and other groups at risk due to high frequency of occupational or nonoccupational contacts; and should also address any essential partnerships with academic, commercial, and hospital laboratories to successfully meet testing demand. Plans should explicitly detail how a minimum of 2% of the state's population will be tested each month beginning immediately; as well as plans to increase that number by Fall 2020. Plans should include a list of established and proposed laboratories that will be testing for SARS-CoV-2 in each state along with each laboratory's available platforms and throughput, that are used for testing and indicate per laboratory, testing projections by month through December 31st, 2020.

In conjunction with optimizing testing and increasing test volumes for COVID-19/SARS-CoV-2, resources will support the establishment of modernized public health surveillance systems. These systems will support the public health response to COVID-19 and lay the foundation for the future of public health surveillance. Establishing systems and processes to report the data categories described in this document on a daily, automated basis to state and federal health systems is a requirement of accepting these funds, if such systems are not already in place. These systems must be transparent and visible to communities through an open website. For each data category, minimum required data elements will be specified by CDC for each reportable condition at a later date. These surveillance and data reporting systems must:

- Ensure that real-time, at least daily, complete and accurate test orders and results can be exchanged within the healthcare/public health system and simultaneously reported to CDC and others via automated systems in a machine-readable format. These systems must support reporting of test results at the county or zipcode level with additional data fields as specified by CDC. This includes not only testing for the presence of virus (nucleic acid or antigen testing), but also serological testing documenting past infection.
- Ensure real-time, at least daily, complete, automated reporting in a machine-readable format for the following data categories: case, hospitalization and death reporting; emergency department syndromic surveillance; and capacity, resources, and patient impact at healthcare facilities through electronic reporting.
- Support the display of up-to-date, critical public health information relating to COVID-19 and future outbreaks at the county or zipcode level in visual dashboards on county or state websites, including case data and syndromic surveillance data.

Enhancements to epidemiologic activities resulting from additional test data are also fundamental to controlling the spread of COVID-19. Recipients must accelerate efforts to conduct robust contact tracing and then identify and isolate new cases of COVID-19 among symptomatic or asymptomatic individuals. This information should be further utilized to understand COVID-19/SARS-CoV-2 exposure within a community and determine appropriate mitigation strategies.

FUNDING STRATEGY

Funding by jurisdiction will be based on population and number of cases of COVID-19/SARS-CoV-2, as further provided in the legislative language for the Paycheck Protection Program and Health Care Enhancement Act of 2020 (<https://www.congress.gov/bill/116th-congress/house-bill/266/>). Direct Assistance is authorized under CK19-1904²; however, should opportunities for direct assistance be made available, these will be shared broadly with our recipient base and options for providing direct assistance in lieu of financial assistance may be discussed and coordinated with the ELC and the CDC Office of Grant Services (OGS).

²Legislative Authority for CK19-1904: Sections 301 and 317 of the Public Health Service Act (PHS Act), 42 USC, 241 and 247b as amended; and Funding is appropriated under Affordable Care Act (PL 111-148), Title IV, Section 4002 (Prevention and Public Health Fund), Title IV, Section 4002

ELC ENHANCING DETECTION

Recipients should consider requesting the following when developing budgets, in furtherance of award activities:

- Personnel (term, temporary, students, overtime, contract staff, etc.)
- Laboratory equipment and necessary maintenance contracts
- Collection supplies, test kits, reagents, consumables and other necessary supplies for existing testing or onboarding new platforms
- Courier service contracts (new or expansion of existing agreements)
- Hardware and software necessary for robust implementation of electronic laboratory and surveillance data exchange between recipient and other entities, including healthcare entities, jurisdictional public health and CDC
- Tools that assist in the rapid identification, electronic reporting, monitoring, analysis, and evaluation of control measures to reduce the spread of disease (e.g. GIS software, visualization dashboards, cloud services)
- Reporting and/or enrollment incentives
- Contracts with academic institutions, private laboratories, and/or commercial entities
- Laboratory renovations and minor construction (may be considered for unique cases where conditions do not currently allow for safe or effective testing)

The above list is as an example and does not represent a full list of allowable costs. Any questions about specific budget items should be directed to the OGS and the ELC Project Officer.

Support to Local Health Departments (LHD):

Recipients should work with their LHDs to determine how local needs can be addressed with the overall available resources. Direct ELC recipients may provide financial resources to LHDs within their jurisdiction by way of a contract or other mechanism(s) as available through their Health Department. In addition to financial resources, ELC direct recipients may provide support to LHDs through offering non-financial resources (personnel, supplies, etc.) to address COVID-19/SARS-CoV-2 surveillance, case detection, reporting, response, and prevention needs at the local level.

Supporting Management of Activities and Resources:

The ELC recommends that jurisdictions ensure ELC leadership staff at the recipient level are adequate for the management of this award and its integration with the recipient's overall portfolio of ELC funded activities. A minimum of 1 program manager and 1 budget staff (or equivalents) is suggested for the effective management and implementation of the recipients' proposed activities.

PROCESS FOR WORKPLAN AND BUDGET SUBMISSION

This funding should support ELC Health Care Enhancement activities and the necessary reporting for Budget Period 1 under CK19-1904; however, recipients are reminded that expanded authority³ applies, and activities are likely to take 30 months for completion due to the nature of COVID-19/SARS-CoV-2. Within 30 days of receipt of the Notice of Award (NOA), the recipient is required to submit a workplan and budget describing its proposed activities. Upon submission, budgets and workplans will be reviewed by CDC and feedback will be provided and discussed with the recipient. Any necessary or recommended changes may be agreed upon between the jurisdiction and CDC and documented in REDCap and/or GrantSolutions as necessary.

To appropriately document workplans, budgets, and facilitate recipients meeting the 30-day requirement:

³ Expanded Authority is provided to recipients through 45 CFR Part 75.308 which allows recipients to incur project costs 90 days prior to award, initiate one-time extension to project period, and carryover unobligated balances to subsequent budget periods.

ELC ENHANCING DETECTION

1. Workplan entries will be completed in the 'ELC Enhanced Detection' portal, under 'ELC COVID-19 Projects', in REDCap; and
2. Revised budgets will be completed by using the template provided via GrantSolutions Grant Notes at time of NOA issuance.
 - a. Funds will be awarded under the 'Other' cost category;
 - b. Recipients will adjust the cost category allocations of awarded funds to reflect the areas where financial assistance is needed; and
 - c. Recipients will upload the revised budget into GrantSolutions via a redirection amendment, with a courtesy copy into REDCap 'ELC Enhanced Detection' portal, by the 30-day post award deadline.
 - d. ELC and OGS will process the redirection amendment in GrantSolutions and the recipient will receive a revised NOA reflecting the requested cost category allocations.
3. A letter, indicating that all ELC Governance Team members have both contributed to and agreed upon the workplan and budget submitted, must be signed by all Governance Team Members (hard copy or digital signature) and submitted with the documents in the REDCap portal.

Workplan detail

Additional workplan guidance will be provided to recipients post-award; they will be required to provide a clear and concise description of the time bound strategies and activities they will use to achieve the project's outcomes, including:

1. Description of how 'ELC Enhanced Detection' funding will be used in coordination with funding from CDC's Crisis COVID-19 Notice of Funding Opportunity (NOFO) and ELC CARES.
2. Specify the distinct new or enhanced activities made possible by 'ELC Enhanced Detection'.
3. Plans for how the ELC recipient will work with local jurisdictions to meet local needs that support the entire jurisdiction. These plans must include: description of activities to be supported at the local level, identification of local partners and localities to be supported, methods to assess local needs, and description of funding mechanisms to support local entities.
4. Description of expected mechanisms and frequency of interactions between the health department and/or public health laboratory with academic/hospital and commercial laboratories.
5. Description of testing plan, including populations and institutional settings. Plans should align to your jurisdictional testing plans for COVID-19 per legislation⁴. Plans for May – June must be submitted by May 30, 2020. Plans for July – December must be submitted by June 15, 2020. Details about testing plan submission will be shared with recipients via the ELC Program office.
6. Description of use of electronic health systems for surveillance, reporting, and public health action.

Of note: In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC responsibilities include but are not limited to:

1. Provide ongoing guidance, programmatic support (including guidance on evaluation, performance measurement, and workplan changes), technical assistance and subject matter expertise to the activities outlined in this supplemental funding announcement guidance.
2. Convene trainings, meetings, conference calls, and site visits with recipients.
3. Share best practices identified and provide national coordination of activities, where appropriate.
4. Coordinate with the HHS Testing Team as needed, for subject matter expertise and technical assistance to support States testing strategies.

In addition to the programmatic activities noted below in further detail, recipient responsibilities include but are not limited to:

⁴ <https://www.congress.gov/bill/116th-congress/house-bill/266/>

ELC ENHANCING DETECTION

1. Regular participation in calls with CDC/HHS for technical assistance and monitoring of activities supported through this cooperative agreement.
2. On-time submission of all requisite reporting. This may include but is not limited to reporting of performance measures and progress on milestones within REDCap or provision of financial updates.
3. Documentation of any necessary budget change/reallocation through REDCap and, as necessary, GrantSolutions.

Both CDC and recipients should appropriately coordinate with points of contact in relevant stakeholder organizations to maximize the impact of federal dollars (e.g., tribal nations, Health Resources and Services Administration (HRSA), HHS testing team, etc.).

ACTIVITIES

Data collected as a part of the Activities supported with these funds shall be reported to CDC in a form and fashion to be determined and communicated at a later date. Recipients are required to establish electronic reporting systems to support comprehensive, timely, automated reporting of these data to LHD, CDC and others, at a frequency to be determined and communicated at a later date, if such systems are not already in place. Such systems must support reporting for COVID-19, other conditions of public health significance.

Activities supported by these funds include but are not limited to the following:

Enhance Laboratory, Surveillance, Informatics and other Workforce Capacity

1. Train and hire staff to improve laboratory workforce ability to address issues around laboratory safety, accessioning, testing and reporting results.
2. Build expertise for healthcare and community outbreak response and infection prevention and control (IPC) among local health departments.
3. Train and hire staff to improve the capacities of the epidemiology and informatics workforce to effectively conduct surveillance and response of COVID-19 (including contact tracing) and other conditions of public health significance.
4. Build expertise to support management of the COVID-19 related activities within the jurisdiction and the integrate into the broader ELC portfolio of activities (e.g., additional leadership, program and project managers, budget staff, etc.).
5. Increase capacity for timely data management, analysis, and reporting for COVID-19 and other conditions of public health significance.

Strengthen Laboratory Testing

1. Establish or expand capacity to quickly, accurately and safely test for SARS-CoV-2/COVID-19 (which may build capacity to test for other pathogens with potential for broad community spread) among all symptomatic individuals, and secondarily expand capacity to achieve community-based surveillance, including testing of asymptomatic individuals.
 - a. Develop systems to improve speed and efficiency of specimen submission to clinical and reference laboratories.
 - b. Strengthen ability to quickly scale testing as necessary to ensure that optimal utilization of existing and new testing platforms can be supported to help meet increases in testing demand in a timely manner.
 - c. Perform serology testing with an FDA EUA authorized serological assay in order to conduct surveillance for past infection and monitor community exposure.
 - d. Work with LHDs to build local capacity for testing of COVID-19/SARS-CoV-2 including within high-risk settings or in vulnerable populations that reside in their communities.

ELC ENHANCING DETECTION

- e. Apply laboratory safety methods to ensure worker safety when managing and testing samples that may contain SARS-CoV-2/COVID-19.
2. Enhance laboratory testing capacity for SARS-CoV-2/COVID-19 outside of public health laboratories
 - a. Establish or expand capacity to coordinate with public/private laboratory testing providers, including those that assist with surge and with testing for high-risk environments.
 - b. Secure and/or utilize mobile laboratory units, or other methods to provide POC testing at public health-led clinics or non-traditional test sites (e.g., homeless shelters, food processing plants, prisons, Long Term Care Facilities (LTCF), etc.).
 3. Enhance data management and analytic capacity in public health laboratories to help improve efficiencies in operations, management, testing, and data sharing.
 - a. Improve efficiencies in laboratory operations and management using data from throughput, staffing, billing, supplies, and orders. Ensure ability to track inventory of testing reagents by device/platform, among other things.
 - b. Improve the capacity to analyze laboratory data to help understand and make informed decisions about issues such as gaps in testing and community mitigation efforts. Data elements such as tests ordered and completed (including by device/platform), rates of positivity, source of samples, specimen collection sites, and test type will be used to create data visualizations that will be shared with the public, local health departments, and federal partners.

Advance Electronic Data Exchange at Public Health Labs

1. Enhance and expand laboratory information infrastructure, to improve jurisdictional visibility on laboratory data (tests performed) from all testing sites and enable faster and more complete data exchange and reporting.
 - a. Employ a well-functioning Laboratory Information Management System (LIMS) system to support efficient data flows within the PHL and its partners. This includes expanding existing capacity of the current LIMS to improve data exchange and increase data flows through LIMS maintenance, new configurations/modules, and enhancements. Implement new/replacement LIMS where needed.
 - b. Ensure ability to administer LIMS. Ensure the ability to configure all tests that are in LIMS, including new tests, EUAs, etc., in a timely manner. Ensure expanding needs for administration and management of LIMS system are covered through dedicated staff.
 - c. Interface diagnostic equipment to directly report laboratory results into LIMS
 - d. Put a web portal in place to support online ordering and reporting. Integrate the web portal into the LIMS.
 - e. Enhance laboratory test ordering and reporting capability.
 - i. Implement or improve capacity to consume and produce electronic HL7 test orders and result reporting (ETOR) to allow laboratories and healthcare providers to directly exchange standardized test orders and results across different facilities and electronic information systems using agreed upon standards.
 - ii. 100% of results must be reported with key demographic variables including age/gender/race
 - iii. Report all testing to the health department and CDC using HL7 ELR.

Improve Surveillance and Reporting of Electronic Health Data

Conducting the activities in this section to enable comprehensive, automated, daily reporting to the CDC and others in a machine-readable format, for data elements to be determined at a later date, is a requirement of accepting these funds.

1. Establish complete, up-to-date, automated reporting of morbidity and mortality to CDC and others due to COVID-19 and other conditions of public health significance, with required associated data fields in a machine readable format, by:
 - a. Establishing or enhancing community-based surveillance, including surveillance of vulnerable populations, individuals without severe illness, those with recent travel to high-risk locations, or who are contacts to known cases.
 - b. Monitoring changes to daily incidence rates of COVID-19 and other conditions of public health significance at the county or zipcode level to inform community mitigation strategies.
2. Establish complete, up-to-date, timely, automated reporting of individual-level data through electronic case reporting to CDC and others in a machine-readable format (ensuring LHD have access to data that is reported):
 - a. At the health department, enhance capacity to work with testing facilities to onboard and improve electronic laboratory reporting (ELR), including to receive data from new or non-traditional testing settings. Use alternative data flows and file formats (e.g., CSV or XLS) to help automate where appropriate. In addition to other reportable results, this should include all COVID-19/SARS-CoV-2-related testing data (i.e., tests to detect SAR-CoV-2 including serology testing).
 - b. Automate receiving EHR data, including eCR and FHIR-base eCR Now, to generate initial case report as specified by CDC for the reportable disease within 24 hours and to update over time within 24 hours of a change in information contained in the CDC-directed case report, including death. Utilize eCR data to ensure data completeness, establish comprehensive morbidity and mortality surveillance, and help monitor the health of the community and inform decisions for the delivery of public health services.
 - c. Increase connectivity with laboratory and healthcare feeds for epidemiologic analysis (including using automated single CSV files).
 - d. Expand eCR etc to include all conditions of public health significance
3. Improve understanding of capacity, resources, and patient impact at healthcare facilities through electronic reporting.
 - a. Required expansion of reporting facility capacity, resources, and patient impact information, such as patients admitted and hospitalized, in an electronic, machine-readable, as well as human-readable visual, and tabular manner, to achieve 100% coverage in jurisdiction and include daily data from all acute care, long-term care, and ambulatory care settings. Use these data to monitor facilities with confirmed cases of COVID-19/SARS-CoV-2 infection or with COVID-like illness among staff or residents and facilities at high risk of acquiring COVID-19/SARS-CoV-2 cases and COVID-like illness among staff or residents.
 - b. Increase ADT messaging and use to achieve comprehensive surveillance of emergency room visits, hospital admissions, facility and department transfers, and discharges to provide an early warning signal, to monitor the impact on hospitals, and to understand the growth of serious cases requiring admission.
4. Enhance systems for flexible data collection, reporting , analysis, and visualization.
 - a. Implement new/replacement systems where needed. Ensure systems are interoperable and that data are able to be linked across systems, including adding the capacity for lab data and other data to be used by the software/tools that are being deployed for contact tracing.
 - b. Data must be made available at the local, state, and federal level.
 - c. Make data on case, syndromic, laboratory tests, hospitalization, and healthcare capacity available on health department websites at the county/zip code level in a visual and tabular manner.
5. Establish or improve systems to ensure complete, accurate and immediate (within 24 hrs) data transmission to a system and open website available to local health officials and the public by county

and zipcode, that allows for automated transmission of data to the CDC in a machine readable format.

- a. Track and send 100% of emergency department and outpatient visits for COVID-like illness, as well as other syndromes/illnesses, to CDC.
- b. Submit comprehensive syndromic surveillance data for all facilities in the jurisdiction.
- c. Send deidentified copies of all admit, discharge, and transfer (ADT) messages to the CDC
- d. Submit all case reports in an immediate, automated way to CDC for COVID-19/SARS-CoV-2 and other conditions of public health significance with associated required data fields in a machine-readable format.
- e. Provide accurate accounting of COVID-19/SARS-CoV-2 associated deaths. Establish electronic, automated, immediate death reporting to CDC with associated required data fields in a machine-readable format.
- f. Report requested COVID-19/SARS-CoV-2-related data, including line level testing data (negatives, positives, indeterminants, serology, antigen, nucleic acid) daily by county or zipcode to the CDC-designated system.
- g. Establish these systems in such a manner that they may be used on an ongoing basis for surveillance of, and reporting on, other threats to the public health and conditions of public health significance.

Use Laboratory Data to Enhance Investigation, Response and Prevention

1. Use laboratory data to initiate case investigations, conduct contact tracing and follow up, and implement containment measures.
 - a. Conduct necessary contact tracing including contact elicitation/identification, contact notification, and contact follow-up. Activities could include traditional contact tracing and/or proximity/location-based methods, as well as methods adapted for healthcare-specific and congregate settings.
 - b. Utilize tools (e.g., geographic information systems and methods) that assist in the rapid mapping and tracking of disease cases for timely and effective epidemic monitoring and response, incorporating laboratory testing results and other data sources.
2. Identify cases and exposure to COVID-19 in high-risk settings or within vulnerable populations to target mitigation strategies.
 - a. Assess and monitor infections in healthcare workers across the healthcare spectrum.
 - b. Monitor cases and exposure to COVID-19 to identify need for targeted mitigation strategies to isolate and prevent further spread within high-risk healthcare facilities (e.g., hospitals, dialysis clinics, cancer clinics, nursing homes, and other long-term care facilities, etc.).
 - c. Monitor cases and exposure to COVID-19 to identify need for targeted mitigation strategies to isolate and prevent further spread within high-risk employment settings (e.g., meat processing facilities), and congregate living settings (e.g., prisons, youth homes, shelters).
 - d. Work with LHDs to build local capacity for reporting, rapid containment and prevention of COVID-19/SARS-CoV-2 within high-risk settings or in vulnerable populations that reside in their communities.
3. Implement prevention strategies in high-risk settings or within vulnerable populations (including tribal nations) including proactive monitoring for asymptomatic case detection.
 - a. Build capacity for infection prevention and control in LTCFs (e.g., at least one Infection Preventionist (IP) for every facility) and outpatient settings.
 - i. Build capacity to safely house and isolate infected and exposed residents of LTCFs and other congregate settings.
 - ii. Develop interoperable patient safety information exchange systems.
 - iii. Assist with enrollment of all LTCFs into NHSN and provision of related user support.
 - b. Increase Infection Prevention and Control (IPC) assessment capacity onsite using tele-ICAR.
 - c. Perform preparedness assessment to ensure interventions are in place to protect high-risk populations.

ELC ENHANCING DETECTION

- a. Coordinate as appropriate with federally funded entities responsible for providing health services to vulnerable populations (e.g., tribal nations and federally qualified health centers)

Coordinate and Engage with Partners

1. Partner with LHDs to establish or enhance testing for COVID-19/SARS-CoV-2.
 - a. Support appropriate LHDs with acquiring equipment and staffing to conduct testing for COVID-19/SARS-CoV-2.
 - b. Support LHDs to conduct appropriate specimen collection and/or testing within their jurisdictions.
2. Partner with local, regional, or national organizations or academic institutions to enhance capacity for infection control and prevention of COVID-19/SARS-CoV-2.
 - a. Build infection prevention and control and healthcare outbreak response expertise in LHDs.
 - b. Partner with academic medical centers and schools of public health to develop regional centers for IPC consultation and support services

PERFORMANCE MEASURES AND REPORTING

Performance Measures: In addition to the metrics and deliverable indicated above, performance measures specific to COVID-19-related activities will be finalized and provided to recipients within 21 days of award. The ELC will utilize existing data sources whenever possible to reduce the reporting burden on recipients and, where appropriate, existing ELC performance measures may be used. While more frequent reporting may be employed within the first year of this supplement, these requirements may be adjusted as circumstances allow. Where it is possible, reporting will be aligned to current performance measure reporting timelines.

Consistent with current ELC practice, progress on Milestones will be reported on a quarterly basis utilizing REDCap. Recipients will be provided 2 weeks to update their progress and note any challenges encountered since the previous update. Financial reporting requirements shall be noted and, as necessary, updated in the Terms and Conditions of the award. The ELC will work with OGS to limit the administrative burden on recipients.

Summary of Reporting Requirements:

1. Quarterly progress reports on milestones in approved workplans via REDCap.
2. Monthly fiscal reports (beginning 60 days after NOAs are issued).
3. Performance measure data.
4. CDC may require recipients to develop annual progress reports (APRs). CDC will provide APR guidance and optional templates should they be required.

Please also note: Data collected as a part of the activities supported with these funds shall be reported to CDC in a form and fashion to be determined and communicated at a later date.

**U.S. Department of Health and Human Services
Report to Congress: COVID-19 Strategic Testing Plan**

- ⁱ The White House. Guidelines for Opening Up America Again: Testing Overview. Retrieved from: <https://www.whitehouse.gov/wp-content/uploads/2020/04/Testing-Overview-Final.pdf>
- ⁱⁱ The White House. Opening Up America Again: Testing Blueprint. Retrieved from: <https://www.whitehouse.gov/wp-content/uploads/2020/04/Testing-Blueprint.pdf>
- ⁱⁱⁱ World Health Organization. Global surveillance for COVID-19 caused by human infection with COVID-19 virus (Interim guidance). Retrieved from: <https://www.who.int/publications-detail/global-surveillance-for-covid-19-caused-by-human-infection-with-covid-19-virus-interim-guidance>
- ^{iv} Centers for Disease Control and Prevention (CDC). Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19) Retrieved from: <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html>
- ^v CDC. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19). Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>
- ^{vi} Edmond J. Safra Center for Ethics. COVID-19 Rapid Response Impact Initiative - White Paper 6: Why We Must Test Millions a Day. Retrieved from: https://ethics.harvard.edu/files/center-for-ethics/files/white_paper_6_testing_millions_final.pdf
- ^{vii} Michael Ryan, executive director of the WHO Health Emergencies Program, March 10, 2020.
- ^{viii} CVS Health. CVS Health to significantly expand COVID-19 testing capabilities. April 27, 2020. Retrieved from: <https://cvshealth.com/newsroom/press-releases/cvs-health-significantly-expand-covid-19-testing-capabilities>
- ^{ix} CDC. Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19). Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html>
- ^x CDC. Testing Guidance for Nursing Homes. Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html>
- ^{xi} Centers for Medicare & Medicaid Services (CMS). Trump Administration Issues Guidance to Ensure States Have a Plan in Place to Safely Reopen Nursing Homes. May 18, 2020. Retrieved from: <https://www.cms.gov/newsroom/press-releases/trump-administration-issues-guidance-ensure-states-have-plan-place-safely-reopen-nursing-homes>
- ^{xii} CDC. COVID-19 Serology Surveillance Strategy. Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/serology-surveillance/index.html>
- ^{xiii} CDC. COVID-19 Infection Control. Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html>
- ^{xiv} CDC and OSHA. COVID-19 Interim Guidance from CDC and the Occupational Safety and Health Administration (OSHA). Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/meat-poultry-processing-workers-employers.html>
- ^{xv} Department of Homeland Security. Critical Infrastructure Sectors. Retrieved from: <https://www.cisa.gov/critical-infrastructure-sectors>
- ^{xvi} Characteristics of Health Care Personnel with COVID-19 — United States, February 12–April 9, 2020. MMWR Morb Mortal Wkly Rep 2020;69:477–481. DOI: <http://dx.doi.org/10.15585/mmwr.mm6915e6>
- ^{xvii} Dyal JW, Grant MP, Broadwater K, et al. COVID-19 Among Workers in Meat and Poultry Processing Facilities — 19 States, April 2020. MMWR Morb Mortal Wkly Rep 2020;69:557–561. DOI: <http://dx.doi.org/10.15585/mmwr.mm6918e3>
- ^{xviii} FDA. Important Information on the Use of Serological (Antibody) Tests for COVID-19 - Letter to Health Care Providers. Retrieved from: <https://www.fda.gov/medical-devices/letters-health-care-providers/important-information-use-serological-antibody-tests-covid-19-letter-health-care-providers>
- ^{xix} FDA. Insight into FDA’s Revised Policy on Antibody Tests: Prioritizing Access and Accuracy. Retrieved from: <https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy>
- ^{xx} FDA. Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency. Retrieved from: <https://www.fda.gov/media/135659/download>
- ^{xxi} FDA. Emergency Use Authorizations. Retrieved from: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations# covid19ivd>
- ^{xxii} CMS. CMS-5531-IFC. Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional

**U.S. Department of Health and Human Services
Report to Congress: COVID-19 Strategic Testing Plan**

Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program. Retrieved from: <https://www.cms.gov/files/document/covid-medicare-and-medicaid-ifc2.pdf>

^{xxiii} CMS. Frequently Asked Questions (FAQs), CLIA Guidance During the COVID-19 Emergency. Retrieved from: <https://www.cms.gov/files/document/cli-laboratory-covid-19-emergency-frequently-asked-questions.pdf>

^{xxiv} Liu, L., Li, Y., Li, S., Hu, N., He, Y., Pong, R., Lin, D., Lu, L., & Law, M. (2012). Comparison of next-generation sequencing systems. *Journal of biomedicine & biotechnology*, 2012, 251364. <https://doi.org/10.1155/2012/251364>

^{xxv} FDA. EUA for Sherlock CRISPR SARS-CoV-2 Kit. Retrieved from: <https://www.fda.gov/media/137747/download>

^{xxvi} Medical Countermeasures.gov. Request ad USG Coronawatch Meeting. Retrieved from: <https://www.medicalcountermeasures.gov/request-barda-techwatch-meeting/>

^{xxvii} CDC. Coronavirus Disease 2019 (COVID-19) – Cases in the U.S. Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html>

^{xxviii} CDC. COVID-19 Death Data and Resources. Retrieved from: <https://www.cdc.gov/nchs/nvss/covid-19.htm>

^{xxix} CDC. Testing Data in the U.S. <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/testing-in-us.html>

^{xxx} FDA. Emergency Use Authorizations. Retrieved from: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations# covid19ivd>

^{xxxi} The Public Health Emergency Preparedness grant formula is from section 319-1(h) of the Public Health Security Act: for the first fiscal year SLTTs cover 5 % of the costs (\$1 spending by SLTT is supported by \$20 of HHS funding), with subsequent fiscal years requiring SLTTs to cover 10 % of the costs (\$1 spending by SLTT is supported by \$10 of HHS funding)

^{xxxii} CMS. Ruling 2020-01-R. April 14, 2020. Retrieved from: <https://www.cms.gov/files/document/cms-2020-01-r.pdf>

^{xxxiii} Prendergast, C. and J. Papenburg (2013). "Rapid antigen-based testing for respiratory syncytial virus: moving diagnostics from bench to bedside?" *Future Microbiol* 8(4): 435-444.

^{xxxiv} Cheng, M. P., et al. (2020). "Diagnostic Testing for Severe Acute Respiratory Syndrome-Related Coronavirus-2: A Narrative Review." *Ann Intern Med*.

^{xxxv} FIND. SARS-CoV-2 Diagnostic Pipeline. Accessed at www.finddx.org/covid-19/pipeline on 4 May 2020

^{xxxvi} Bao, L., et al. (2020). "Reinfection could not occur in SARS-CoV-2 infected rhesus macaques." *bioRxiv*: 2020.2003.2013.990226.