



MEMORANDUM

May 14, 2020

To: Governors' Offices
From: Bill McBride, Executive Director
Re: Capacity for COVID-19 Testing -- Current Status and Considerations

This document is an update to NGA's March 26 memo on testing, which provided comprehensive historical information.

COVID-19 testing is essential to a targeted public health approach for informing clinical care and reducing spread of the virus until a vaccine is available. Current testing capacity is notably insufficient to meet these demands, and limited supply is typically prioritized for people with symptoms, health care workers, first responders and vulnerable populations.

This memo provides current information regarding COVID-19 testing and test capacity and strategies governors may consider as they work to increase that capacity in their states for both short-term and long-term needs. You can find an overview of this memo here.

Contents

Background: Current COVID-19 Testing Constraints and Projected Need 2
Strategies for Governors Consideration 2
Expand access to multiple forms of tests and laboratory capacity 2
Partner to acquire testing equipment and supplies 5
Use a public health approach to prioritize testing while supplies are limited 6
Pursue public-private partnerships to establish drive-through and walk-up testing sites 7
Prepare and plan for the next phase of response 8
Surveillance 8
Preparing for reopening: 10
Testing and Coverage 11
Appendix 12
Overview of Current Type of Testing and New Notable Tests 12
Rapid Point of Care Tests: 12
High-throughput tests: 12
Serologic testing 13
At-home tests 13
CRISPR-based rapid testing: 14
Additional Resources 14



Background: Current COVID-19 Testing Constraints and Projected Need

Widespread testing capacity has been severely limited by shortages in testing components, including reagents, swabs and other test equipment, and personal protective equipment needed for test administrators. Other obstacles include bottlenecks at laboratories due to high volume (which are beginning to improve at high-throughput laboratories), notable [concerns](#) about accuracy of test results, and equipment and human resource needs to shift to dedicated COVID-19 test development and processing. Experts note that capacity is expected to ramp up significantly with the introduction of rapid, point-of-care (POC) tests, which operate on existing, ubiquitous platforms and produce results in minutes, the possibility of reliable at-home testing, and rapid antigen testing (see

Appendix for more information). But the pace of scaling POC testing is tied to operational shifts in manufacturing toward COVID-19 exclusive production and broader considerations about sensitivity of tests to detect the virus. Serologic tests, which detect antibodies to the virus in the blood, are being added to the arsenal for surveillance approaches to assess prevalence in the community and changes in immunological response over time. This technology is also evolving, and additional research is needed to understand the behavior of the virus, our immune response to it, and what serological tests can tell us.

For now, limited access to testing requires prioritization protocols at the vast majority of testing locations (see [below](#)). Some experts project testing may reach sufficient capacity in the next few months, allowing for a pivot to gradual relaxation of aggressive social distancing measures, provided that testing and background surveillance is paired with a robust case identification and contact tracing infrastructure and targeted isolation policies. However, the timing is directly tied to the projected volume needed to achieve reopening plans. In the U.S., testing averages about [250,000 people per day](#) (or 1.5 per 1000 people). Estimated capacity needed for gradual reopening ranges from [750,000 tests per week to 5-20 million per day](#). Assuming the midpoint of that range, current U.S. capacity is exponentially less than needed.

Harvard's Global Health Institute, in partnership with NPR, released [updated estimates](#) of the number of tests that states should aim to be completing per day by May 15 in order to safely reopen parts of their state. In sum, they estimate that the U.S. should be doing more than 900,000 tests per day (the U.S. is currently testing around 250,000 per day according to data from the [COVID Tracking project](#)). Importantly, each state's specific testing estimates vary based on the size of the outbreak in their communities and current testing capacity. The estimates serve as a minimum since they assume that physical distancing will continue through May 15 and a number of states have gradually begun to lift restrictions. The report includes a [widget](#) that allows users to look at their specific state and a [graphic](#) that includes all states and the current size of their outbreak, current daily testing compared to Harvard's estimated target daily testing, and their positive test ratio compared to a target of 10 percent or less. The authors note that testing is an important component together with case numbers and adequate contact tracing and isolation supports. The report compares states across three different testing models and there are different projections; but all say that most states are not at the optimal levels for testing capacity.

Strategies for Governors' Consideration

Expand access to multiple forms of tests and laboratory capacity to process tests through public and private laboratories. Please see the

Appendix for more detail about the types of tests currently available and of new and notable tests.

- **Continue to request the federal government to rapidly build testing capacity and coordinate distribution to states.** Individually and through NGA, the governors have already [called on](#) the federal government to enable states to obtain and allocate vital medical equipment and supplies without causing inter-state competition. In addition, governors have requested rapid and exponential increase in availability of COVID-19 tests and testing equipment, fully financed by the federal government, and with federally coordinated allocation. Governors should continue to urge the administration to fully implement the Defense Production Act (DPA) to ensure national access to testing continues to be an option.
 - The [Paycheck Protection Program and Health Care Enhancement Act](#) (PPHEA) was enacted on April 24. The package includes \$25 billion for testing (and other related activities such as contact tracing and surveillance), \$11 billion¹ of which would go to the states, localities, territories, tribal organizations, urban Indian health organizations, or health service providers to tribes for developing, purchasing, administering, processing, and analyzing tests as well as for surveillance, contact tracing and other testing related activities. States, localities, territories, and tribes receiving funds will be required to submit a plan for testing that includes the state's goals for the remainder of the calendar year and 1) the number of diagnostic, serologic, and other tests needed by month; 2) estimates of laboratory and testing capacity (including workforce, equipment, supplies, and available tests) by month; and 3) a description of how the state will use its resources for testing, including related community mitigation policies. The plan also needs to address states' needs for contact tracing, surveillance and related activities. On May 14, HHS sent a [letter](#) requiring states to submit testing plans by May 30, 2020 along with a [template](#) with additional information. Each plan must align with the [Opening Up America Again Guidelines](#). The White House announced on May 11 that the funds will be distributed based on a formula that considers the states' population as well as prevalence of coronavirus. The White House also announced that states should aim to test 2% of their populations in May and that they will provide 12.9 million swabs and 10 million tubes of transport media
 - The other \$11 billion would go to the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) for development and deployment of testing. The bill also requires the federal government to report disaggregated data and develop a national strategic plan for increasing domestic testing capacity, addressing disparities, and providing assistance and resources to states, localities, territories, and tribes.
 - The Health Resources and Services Administration (HRSA) awarded nearly \$583 million to 1,385 HRSA-funded health centers across U.S. states and territories on May 7, as authorized under the Paycheck Protection Program and Health Care Enhancement Act. HRSA reports that 88 percent of health centers are offering testing and 65 percent are offering walk-up or drive-through options. Find the list of award recipients [here](#).
 - The White House released the Opening Up America Again [Testing Overview](#) and [Testing Blueprint](#) to accompany the president's [Guidelines for Opening Up America Again](#) on April 27. The Blueprint lays out roles and responsibilities, principles, and elements of a robust testing and rapid response program to ensure every symptomatic patient receives a timely and accurate diagnostic test. The plan

¹ Of this total: \$4.25 billion is allocated to states based on the prevalence of COVID-19 cases; \$2 billion is allocated to states based on the formula applicable to the Public Health Emergency Preparedness cooperative agreement; and \$750 million is allocated to tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes.

The remainder of the funding will be designated as follows: \$1 billion for the CDC; \$1.8 billion for the NIH, which includes \$306 million to the National Cancer Institute, \$500 million to the National Institute of Biomedical Imaging and Bioengineering and \$1 billion to the Office of the Director; \$1 billion for the Biomedical Advanced Research and Development Authority; \$22 million for the FDA; \$600 million to HRSA for Community Health Centers; \$225 million for rural health clinics; \$1 billion to cover testing for the uninsured, which adds to the National Disaster Medical System (NDMS) funding provided for such purposes in the CARES Act; and more than \$8 billion remains undesignated, and HHS has discretion to spend it on various COVID-19 testing needs.

reinforces that the federal government should act as the supplier of last resort and states should maximize the use of all available testing platforms and venues. The blueprint also provides recommendations on the use of antibody testing, including using the aggregation of two successive tests to increase accuracy and reliability. However, it notes that additional research is needed on immune response to the virus and on the accuracy of tests.

- NIH announced their [Rapid Acceleration of Diagnostics \(RADx\) program](#) on April 29, which aims to speed the development of highly accurate tests. The initial step in the RADx program will be a national competition in the style of “shark tank” with participants vying for a portion of the \$500 million fund. NIH aims to have the resulting tests deployed by the end of summer or early fall after validation, clinical tests, and manufacturing scale up.
- Food and Drug Administration (FDA) updated their [FAQs on emergency use authorizations \(EUA\)](#) to clarify that all EUAs will no longer be in effect once the public health emergency is terminated.
- **Consider a cooperative purchasing and distribution approach.** Absent a federal coordinating role, a multi-state cooperative procurement and allocation approach may be considered, which has also been suggested for obtaining personal protective equipment (PPE) and medical supplies. Multi-jurisdictional purchasing arrangements to leverage volume and increase purchasing power are routine (e.g., for purchasing office supplies or pharmaceuticals). Group purchasing organizations (such as [MMCAP Infuse](#) or [NASPO ValuePoint](#)), which already contract with states and have established partnerships with large wholesalers and distributors, could serve as the infrastructure for this purpose under the direction of a governors’ collaborative. When wide-scale test capacity is reached, procurement and distribution practices can return to business as usual. Alternatively, a regional approach, like that [initiated](#) by some governors in the Northeast, could serve this purpose.
 - Governor Cuomo [announced](#) on May 3 that seven northeast states were forming a purchasing cooperative to buy \$5 billion worth of equipment, testing, and supplies.
- **Continue building test capacity in your states.** Governors may authorize laboratories to develop and process tests under [guidance](#) from the U.S. Food and Drug Administration (FDA) to supplement production in public health laboratories. Many university laboratories are developing their own tests and test components, including taking advantage of self-administered nasal swab collection per guidance from the FDA and the CDC. For example, they are developing saliva collection methods in [New York](#), and New Jersey has opened its first drive-through testing site using saliva testing [developed by Rutgers University](#) (the first authorized by the FDA). Some academic laboratories have [untapped capacity](#) due to administrative, regulatory or logistical challenges associated with fragmented health care systems and inability to communicate their availability. Other laboratories are developing antibody tests but are awaiting approval from the FDA. For example, Arizona Governor Doug Ducey [announced](#) a partnership with the University of Arizona to provide antibody tests to health care professionals and first responders. (See [NGA’s March 26 testing memo](#) for more detail).

In addition, governors continue to forge their own partnerships to acquire needed tests.

- For example, Maryland Governor Larry Hogan [announced](#) on Apr 20 that Maryland received 500,000 test kits from South Korea.
- Minnesota Governor Tim Walz [announced](#) a statewide testing strategy to test symptomatic people (up to 20,000 diagnostic tests and 15,000 serology tests per day), isolate confirmed cases, and expand contact tracing in preparation for moving towards controlling the pandemic and reopening the state. The initiative is a partnership between the state, the Mayo Clinic, and the University of Minnesota. Lt Governor Peggy Flanagan emphasized testing would be crucial for vulnerable populations including those living or working in congregate care settings or experiencing homelessness, communities of color, American Indians, and essential workers.
- [California](#) and [Connecticut](#) each formed state task forces to lead the development, sourcing and distribution of tests.

- New York Governor Andrew Cuomo [signed](#) an executive order directing all public and private labs in New York to coordinate with the state department of health to prioritize coronavirus diagnostic testing.
- **Work with state health officials to monitor test performance to inform testing policies.** The need for rapid escalation of testing beginning in February led the FDA to issue [guidance](#) on diagnostic test development and analysis to facilitate rapid emergency use approvals and allow for state authorization of tests. While the data are emerging, one preliminary [study](#) from China indicates at least a 30 percent false negative rate, and growing [anecdotal evidence](#) in the United States suggests a similar rate. False negatives may result from timing of specimen collection (too early or late in infection), improper sample collection, or issues in storage and transport. In general, concerns about accuracy of results from existing diagnostic tests suggests that a balance between rapid development and deployment and careful assessment of test reliability is needed.

Partner to acquire testing equipment and supplies such as reagents, swabs and personal protective equipment (PPE). Shortages in testing equipment, swabs, reagents and PPE are beginning to alleviate, but remain a challenge in many areas of the country.

- **Swabs and viral transport media.** The FDA has [approved](#) additional types of swabs for use when validated by the individual lab with the specific test being used, and [CDC guidance was updated to allow](#) self-collection with a nasal swab with oversight by a health worker. LabCorp has validated multiple [types of swabs](#) which they are able to provide to test administrators who send specimens to their labs. In addition, they are available for technical assistance on swabs and other testing shortage questions. University laboratories, states, and others are beginning to manufacture their own swabs, using a combination of 3-D printing technology and sourcing of the collection material at the end of the swab. Similarly, labs are able to produce their own transport media (used in stabilizing the specimen), however, they must be validated and reviewed by FDA prior to use. Many university and private sector laboratories are producing their own viral transport media and CDC [has made available](#) operating procedures for that purpose.
 - President Trump [announced](#) on April 19 that a large manufacturer of cotton swabs in Ohio will soon convert to producing 10 million swabs per month for testing.
 - The Department of Defense [announced](#) that Puritan Medical Products was awarded a \$75 million DPA Title 3 contract on April 29 to increase swab production by 20 million per month, bringing their total production to 40 million swabs per month starting in May. Puritan is building a new manufacturing facility in Pittsfield, Maine with 150 employees to staff the new factory. Governor Steve Bullock [announced](#) that Montana received 15,000 swabs from FEMA during the last two weeks of April and is expecting another 7,000 swabs in early May.
 - CDC released updated information on [Testing Clinical Specimens from Persons with COVID-19](#). It specifies that viral transport media is not indicated for use with certain point-of-care tests and updates guidance on the types of swabs that may be used.
- **Reagents.** Following March 16 FDA [guidance](#) that states may set up their own systems to authorize COVID-19 test development, some university scientist teams are producing reagents needed in testing for the COVID-19 virus. (See NGA [memo](#) on University production of reagents.) Experts note that universities with core lab capacity are better positioned with equipment, space, personnel and material resources needed for the complex process of producing reagents and that certain reagents are more easily produced than others. The [University of Virginia](#), [Stanford University](#) and [New York University](#) have leveraged and shifted internal resources to be able to manufacture needed reagents for their own tests. For laboratories with less ability to manufacture their own reagents, it may be possible to partner with diagnostics manufacturers who can ramp up quantity without compromising test integrity through good manufacturing principles.

- **PPE.** States should consider including testing sites/personnel among those prioritized for PPE distribution acquired through multiple channels, including requests to the federal government, partnership with private entities and collaboratives triaging need and available, vetted sources. Please see the NGA memo on [Governors Actions to Address PPE and Ventilator Shortage](#). In addition, there is a push for scaling up testing that requires less PPE, such as through self-swabs, at-home collection, or through saliva samples.
- **Alternative specimen collection approaches.** Self-contained POC tests that do not require additional reagents (e.g., Abbott’s POC test) and those that do not require swabs (e.g., Cepheid’s POC) are reducing the need for separately sourcing swabs and reagents. Other tests are validated for use with alternative collection approaches including nasal wash sampling (e.g., CDC’s high-throughput test) which some argue may require notable sampling behavior change, or saliva sampling (e.g., Rutgers University [RUCDR Infinite Biologics](#) was authorized by the FDA on April 13 and the FDA also [authorized](#) at-home sample collection on May 8).

In addition, at-home testing approaches can increase access to testing and reduce the need for health care worker oversight, and associated PPE. The first at-home test, from [LabCorp](#), received emergency use authorization from the FDA on Apr 20. Notably, the specimen will be collected at home using a nasal swab and returned to LabCorp for processing. LabCorp [reported on April 21](#) that the first kits will be made available to health care workers and first responders who are symptomatic or may have been exposed to COVID-19. In the coming weeks kits will be made available to consumers.

Use a public health approach to prioritize testing while supplies are limited. This approach is necessary while capacity remains limited. States should communicate a consistent message to the public about who should seek testing and when it is appropriate. Approaches to prioritization may differ by state, depending on the phase of the pandemic and testing capacity.

- Current [federal guidance](#) includes the following priority groups:
 - Hospitalized patients with symptoms
 - Healthcare facility workers, workers in congregate living settings, and first responders with symptoms
 - Residents in long-term care facilities or other congregate living settings, including correctional and detention facilities and shelters, with symptoms
 - Persons identified by public health officials or clinicians as high priority:
 - Persons with symptoms of a possible infection with COVID-19, including fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea, and/or sore throat.
 - Persons without symptoms who come from racial and ethnic minority groups disproportionately affected by adverse COVID-19 outcomes – currently African Americans, Hispanics and Latinos, some American Indian tribes (e.g., Navajo Nation).
 - Persons without symptoms who are prioritized by health departments or clinicians, including but not limited to: public health monitoring, sentinel surveillance, presence of underlying medical condition or disability, residency in a congregate housing setting such as a homeless shelter or long term care facility, or screening of other asymptomatic individuals according to state and local plans.
- Many states have implemented their own prioritization protocols based on their state’s phase of response and access to testing resources. In addition, many of these states have rolled out websites or apps to allow residents to be screened for testing and find testing locations.
 - Utah [recommended](#) that all individuals with fever or signs and symptoms of lower respiratory illness be tested for COVID-19.
 - North Dakota [expanded](#) their priorities to include health care workers, residents and staff at long-term care facilities, other vulnerable populations, and large businesses that have seen positive cases. They are also partnering with tribal nations to conduct test collection events for those communities.

- Wisconsin added critical infrastructure employees (including water, sewer, gas, electric, power generation, distribution of raw materials, and oil and biofuel refining) to the [priority population for testing](#).
- Iowa Governor Kim Reynolds launched [TestIowa.com](#), which includes an online health assessment along with information on drive-through testing and electronic results. The first testing location was scheduled to open on April 22 and additional sites are coming soon. Testing will prioritize first responders and medical personnel; however, they encourage all Iowans to take the assessment (with the #TestIowaChallenge) to give state leaders insight into hot spots and where future testing sites should be located.
- Nebraska rolled out [testnebraska.com](#) which allows residents to assess their need for testing and provide information to public health about the level of need for testing; schedule appointments and identify drive through testing locations; and track information about infection and contacts.
- [Experts](#) have indicated that testing priorities should include vulnerable populations such as communities of color, American Indian/Native Americans, and lower-income Americans who may be at risk. Communities of color and lower-income Americans are more often essential workers, often live and work in densely populated areas, are more likely to have underlying conditions putting them at higher risk, and have chronic access to healthcare challenges.
- Continued communication with the public regarding testing capacity, the rationale for priority eligibility protocols while supplies are limited, and the role of testing in informing safe relaxation of social distancing restrictions is critical as governors seek to maximize compliance during this critical time.
 - New Mexico [established](#) a self-screening tool, hotline and results portal to accompany its community-based testing to assist individuals with determining whether they require a test.
 - Rhode Island has [expanded](#) testing eligibility to individuals with symptoms and a doctor's referral in the following groups: healthcare workers, hospitalized patients, people living in congregate living settings, people over 65, people with underlying medical conditions, and frontline workers.

Pursue public-private partnerships to establish drive-through and walk-up testing sites. These alternate testing sites alleviate pressure on emergency departments and urgent care centers and prevent further transmission by isolating vulnerable patients from possible cases in those settings. Several testing sites are operational either through health systems in partnership with states, commercial partners, or through the federal public-private partnership initiative for community-based testing sites. Under the latter initiative, as of mid-April, there are 41 community-based testing sites that have screened 81,000 people. Currently these sites are transitioning from federal support to state control. Following concerns raised by governors around a hard deadline for transitioning to being fully state-operated, FEMA is [requesting](#) that states inform the federal government of whether they would like to transition earlier or continue to seek federal support at least until June 1. HHS created a new [webpage](#) with information on community-based testing sites in partnership with retail and pharmacy chains (CVS Health, Kroger, Rite Aid, Walgreens, and Walmart). In addition, commercial partners are establishing drive-through and stationary testing sites in collaboration with states.

- Connecticut, in partnership with the state's six hospital systems, has started 15 ["alternate space sites"](#) located on hospital grounds for testing. The Connecticut Department of Health dedicated two full-time regulatory staff to partner with hospital leadership to review the sites and provide approval. As with other locations, individuals must have a doctor's order for testing.
- Michigan [announced](#) it is expanding or building 13 drive-through testing sites and an additional laboratory for processing tests through a partnership between the Michigan Department of Health and Human Services, Michigan Primary Care Association, 11 health centers, and NxGen MDX Laboratory.
- Tennessee [announced](#) the state, in partnership with the National Guard, will operate 15 drive-through testing sites for anyone regardless of symptoms for the Apr 18-19, Apr 25-26, and May 2-3 weekends.
- CVS [has partnered](#) with four states to establish four drive-through testing sites in partnership with the governors of Georgia, Rhode Island, Massachusetts, and Michigan using Abbott's POC tests. They can run

up to 1,000 tests per day. The [most recent site](#), in Dearborn, Michigan, is part of CVS' and Michigan's efforts to ensure access to testing for underserved communities and communities of color who are disproportionately effected by COVID-19. CVS [announced](#) during the White House coronavirus press briefing that they will begin installing testing in 1,000 CVS stores through the drive-throughs and parking lots in May.

- [Rite Aid](#) also announced their plans to open additional testing sites at their existing store locations utilizing the parking lots and drive through windows. They also expanded COVID-19 testing criteria at all of their testing sites to include adults who are not exhibiting any symptoms of the virus.
- Walgreens [announced](#) plans to open 15 additional drive-through testing sites located in seven states (Arizona, Florida, Illinois, Kentucky, Louisiana, Tennessee and Texas), also using Abbott's POC test, which are expected to open in mid-April.
- [Google](#) and [Apple](#) maps have begun to include testing locations in many states.

As states begin to establish these sites, they should consider the expected number of tests that sites will be able to process, the number of staff needed, and the amount of PPE. Early reporting from one community-based testing site, using tests that must be sent to a lab, indicated that the maximum number of tests per day, per site is 150 and the site requires 20 individuals, all of whom are placed on a 14-day quarantine at the end of their shifts.

- See the Office of the Assistant Secretary for Preparedness and Response (ASPR) technical assistance [memo](#) and ASTHO key considerations [memo](#) for protocols and key considerations.
- Verily released a [program guide](#) with lessons learned and protocols from four California-based drive-through testing locations.

In addition, states should consider that drive-through testing sites may be inaccessible for those without access to a car. In order to make testing more equitable, some localities have introduced "walk-up" or mobile testing sites to address the needs of residents without access to a car.

- Walk-up
 - On April 14, Mercer County, New Jersey, [launched](#) its first walk-up test site in Trenton, New Jersey. The walk-up sites will rotate daily across city wards and are reserved for those residents who cannot utilize the county's drive-through test site.
 - Los Angeles County [opened](#) a walk-up testing site in South Los Angeles on April 14. Another site opened a few weeks earlier in Echo Park.
- Mobile
 - New York [announced](#) a partnership with Ready Responders who use EMTs, nurses, and paramedics to operate a mobile testing program at public housing sites and to provide non-emergent care and connect with providers via telehealth if needed.
 - The city of Harrisonburg is [partnering](#) with the Virginia Department of Health and Sentara Healthcare to bring mobile COVID-19 testing to two neighborhoods to focus on increasing the amount of testing available in diverse neighborhoods.
 - Utah [announced](#) a partnership with the Utah Navajo Health System to deploy a COVID-19 mobile testing team to the Utah portion of the Navajo Nation.
 - CVS [announced](#) they will be developing mobile testing that can be used to target underserved communities and businesses restarting onsite work.
 - Seattle firefighters [started](#) a mobile testing unit to test staff at nursing facilities.

Prepare and plan for the next phase of response. As capacity for testing begins to increase, focus is shifting to surveillance studies to understand the prevalence of the virus in communities, infection rates regardless of symptom status, and how our immune response changes with exposure and time.

Surveillance:

States, localities and the federal government are beginning to implement studies using a representative sample of the population in order to better understand the level of exposure in communities and extrapolate to larger populations. Although multiple testing approaches can be used, methods that avoid the use of diagnostic tests that are in short supply may be most desirable. Serologic testing, which tests for immune response rather than presence of the virus, is being employed in many of these studies. (See

Appendix for more details.) Twelve tests have received emergency use authorization from the FDA, however the agency cautions that test validation should be sought before widespread use. Surveillance will be critical to understand the current pandemic and to monitor the potential for future outbreaks and hot spots.

- Serology studies:
 - The Centers for Disease Control and Prevention ([CDC is beginning](#)) three studies using a CDC-developed serology test to better understand COVID-19 cases that have evaded detection. The first study is already underway and will utilize antibody testing in a sample of undiagnosed individuals in hot spots (New York City and Washington state); the second study will look at a national sample over a longer period of time; and the third study will focus on health care workers. CDC clarified that the test is currently only validated for surveillance and not for individual understanding of past exposure.
 - The National Institute of Health (NIH) launched a national “serosurvey” study which will include up to 10,000 volunteers. Participants will answer a health assessment questionnaire and provide basic demographic information virtually. Samples will be given either the NIH Bethesda campus for participants who work there, or via an at-home collection kit (Mitra® Home Blood Collection Kit from Neoteryx). Participants will then send the samples back to the laboratory for testing.
 - New York Governor Cuomo [announced](#) the completion of a 15,000 sample antibody study conducted at grocery stores and community centers during the last two weeks of April. The preliminary results show that 12.3 percent of the sample had COVID-19 antibodies. The regions with the highest rates were Long Island with 11.4 percent, Westchester/Rockland with 13.8 percent, and New York City with 19.9 percent. The other regions of the state all fell below 6 percent. NYC officials continue to [urge caution](#) when relying on serology testing for policy decision to reopen and especially for individual assessments of immunity.
 - Stanford [began](#) collecting samples from 3,000 individuals in Santa Clara County, California, and is planning further collection in Los Angeles County for use in a serologic study. Revised preliminary [results](#) indicate that 1.5 percent of the sample had antibodies and between 14,000 – 35,000 people in the county were infected, notably higher than the reported 1,000 cases.
 - Miami-Dade County is conducting a [survey](#) using antibody blood tests collected at drive-through testing locations. Each week for several weeks, 750 residents will be tested, with about 3,500 tested over the next month. For more information see NGA’s [memo](#) summarizing the study. [Approximately](#) 6 percent of participants tested positive for COVID-19 antibodies, which if extrapolated equates to 165,000 Miami-Dade County residents.
 - Ohio is [starting](#) a random sample to test for antibodies among 100 asymptomatic people.
 - Arizona Governor Doug Ducey [announced](#) a partnership with the University of Arizona to provide serological testing to 250,000 healthcare professionals. The [first phase of testing](#) began on April 30 in Pima County with 3,000 healthcare workers and first responders. A comparison group of the general public was also included.
 - Beaumont Health’s Research Institute is [launching](#) a widespread, voluntary serological study of its employees and inpatients to understand the extent of infection, answer outstanding questions about the body’s immune response to the virus, and identify individuals as potential donors for plasma infusion treatments.
- Studies using diagnostic testing:
 - Washington launched [SCAN](#) which is conducting testing of a representative sample of people and uses modelling to estimate the number of people infected in the area. Participants answer an online questionnaire and are sent a swab kit which is returned to SCAN for molecular diagnostic testing. SCAN is also testing residual samples taken for other reasons.
 - North Dakota is [starting](#) pilots in two small, rural towns to test asymptomatic people at drive-through test sites. If successful, the state may launch similar programs in metropolitan areas.
- Other surveillance approaches:

- CDC has begun weekly COVID-19 [surveillance reports](#) modeled on its influenza reporting (FluView).
- The White House [framework](#) for reopening America recommends that sentinel surveillance sites screen for asymptomatic cases and contacts and that the sites operate at locations that serve older people, low-income, racial minorities, and Native Americans.
- Connecticut Governor Ned Lamont [announced](#) a new app in Connecticut that will voluntarily ask residents to report their symptoms allowing the state to better track hot spots.

Preparing for reopening:

Several experts have recommended, along with states with specific plans, massive scaling of testing along with contact tracing, surveillance, isolation and quarantine as critical elements of how states may reopen and begin a path to economic recovery. NGA published a [Roadmap to Recovery: A Public Health Guide for Governors](#) with additional details on this topic. A number of governors are beginning to develop plans, all of which rely on mass testing. The manner of collection and how results are used have critical privacy, legal, and ethical considerations.

- **Diagnostic Testing:** Some states, localities, and business have emphasized testing individuals prior to returning to work, co-locating testing with high-risk businesses, or prioritizing workers where testing remains limited. Using diagnostic tests for this purpose may be complicated by [reports](#) that diagnostic tests remain positive long after symptoms fade and virus shedding has ceased.
 - Detroit Mayor Mike Duggan announced that the city will start making diagnostic tests available to all employees of “essential” businesses and to city employees performing essential services.
 - Governor John Carney [announced](#) Delaware is launching a public-private partnership to stand up testing sites in Sussex County at poultry plants and in the community, for poultry workers and workers in other industries and their families. In addition to the testing, individuals who visit the sites will receive care kits that include hand sanitizer, bandanas, thermometers, and educational materials translated into Spanish and Haitian Creole.
 - Amazon [announced](#) it hopes to start testing a small number of its front line employees soon, in addition to other practices such as temperature checks and mask distribution. The company is building incremental testing capacity through assembling equipment to build a laboratory and are moving scientists, managers, procurement officers, and software engineers to be dedicated to the initiative.
 - The president of Brown University, as part of her [op-ed](#) calling for the reopening of universities in the fall, emphasized the need for widespread testing when students return to campus and at regular intervals throughout the year.
- **Serologic Testing:** Some localities and other countries have begun exploring testing protocols that could be used to identify individuals with immunity (using antibody testing). The [FDA](#) and many experts note that both serologic testing and our understanding of immune response, immunity and ongoing risk for contagion requires additional research and test validation protocols. Research is underway [including among federal agencies](#) (FDA, NIH and CDC), but questions remain about how soon after exposure antibodies show up in the bloodstream, at what point in the disease process individuals are no longer spreading the virus, and how long the antibodies will offer protection. To accommodate this, additional testing may be required to measure response and determine if someone is clear of the virus.
 - The Trump administration on April 11 [announced](#) that it will require insurers to provide serology testing free of charge as part of the administration’s push to prepare Americans to return to work. Dr. Anthony Fauci also [indicated](#) that the White House task force is discussing “certificates of immunity” as new serology tests come to the market in the coming weeks.
 - United Biomedical is [offering](#) serological tests to residents of San Miguel County in Colorado on a repeated schedule. If individuals receive a positive result, they are told to isolate since they may not have yet cleared the virus. Another test is done and if positive again they assume they've

- recovered and are immune and return to working on the front lines. Negative results are more challenging since it could mean the individual is too early in the disease process for antibodies.
- German, Italian and British elected officials have [considered](#) using testing to issue documents that identify individuals as having immunity or as having never been infected. Germany has proposed testing 100,000 people and giving immunity certificates to those with antibodies. The Italian region of Veneto is planning on collecting 100,000 blood samples beginning with health care workers and public employees to study the antibody approach.
 - Dubai-based Emirates airlines has [started](#) testing blood for antibodies before flights in order to prepare passengers to enter countries that require immunity passports. It is not clear yet whether decisions about boarding would be influenced by the presence of antibodies.
 - **Fever and other symptom screening:** The federal government and the commercial sector have indicated that expanded use of systems for taking body temperature measurements and other forms of symptom tracking may be helpful in workplaces, airports, etc.
 - The FDA issued [guidance](#) in April intended to expand the availability of advanced temperature systems (which read the body surface temperature and estimate internal body temperature) for triage and use during the public health emergency while other temperature-taking devices are in limited supply. The guidance explains that the FDA will not object to distribution of these technologies without the usual premarket notification and clearance process.
 - The White House framework on reopening recommends that employers implement policies regarding temperature checks.
 - A [group of scientists](#), providing recommendations to the administration on the COVID-19 response, recommend using a national symptom tracking system in which users would input their symptoms every day before going to work or school. Different industries could have different cut off levels depending on level of risk.

Testing and Coverage.

Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, individuals with health insurance coverage through the individual and group insurance markets or with coverage through Medicaid and Medicare are protected from cost sharing requirements for COVID-19 testing. States may consider areas where gaps exist in federal protections against cost barriers and where state action may remove barriers to testing and treatment. States may consider eliminating cost sharing for treatment and other related diagnostic testing, eliminate prior authorization for relevant testing and treatment, and allowing out-of-network care at no additional cost for testing and treatment. States also have the option of expanding their Medicaid programs for uninsured individuals solely for testing and diagnosis of COVID-19. (See FAQs from the Centers for Medicare and Medicaid Services [here](#).)

On April 15, the Centers for Medicare and Medicaid Services (CMS) [announced](#) that Medicare will increase its payment for high-throughput COVID-19 diagnostic tests from \$51 to \$100. Laboratories and testing experts had indicated the change would be important to adequately cover the cost of testing. On April 30, CMS also [announced](#) that new waivers and rule changes include that COVID-19 testing and other tests required as part of a COVID-19 diagnosis would no longer require a physician's order for reimbursement by Medicare. This change facilitates reimbursement for sample collection by pharmacists and at community-based testing sites.

#####

For questions related to the contents of this memo, please contact NGA staff:

- Sandra Wilkniss (swilkniss@nga.org; 312-550-1849)
- Elaine Chhean (echhean@nga.org; 240-426-1298)

Appendix

Overview of Current Type of Testing and New Notable Tests

Antigen Tests: FDA issued the [first EUA](#) for an antigen test on May 9 to Quidel Corporation. Antigen tests look for pieces of the virus in samples taken by nasal swab. These tests are rapid and very specific, but the FDA notes that they are not as sensitive as molecular tests and therefore negative results may need to be confirmed. As these tests begin being developed by multiple manufacturers, they are expected to greatly expand access to rapid testing.

Rapid Point of Care Tests: Recent emergency use authorizations (see more about EUAs [here](#)) include point-of-care (POC) tests which are used to make rapid decisions in clinical settings. POC machines run a limited number of tests at a time but are much more rapid, able to be located within hospitals and physicians' offices, and are self-contained and typically do not require additional materials. In addition to the ones highlighted below, more POC tests are expected to come on the market in the few weeks to a month. POC tests with an EUA include:

- Abbott's [ID NOW COVID-19 test](#), which delivers positive results in five minutes and negative results in 13 minutes. The test platform is small and already used in many settings with a clinical laboratory improvement amendment (CLIA) Certificate of Waiver for influenza and strep testing. However, there are continuing [questions](#) about how the tests are being distributed. Abbott reported that 190,000 test cartridges have shipped, but governors have noted that they have received very few cartridges. On April 9, the federal government began a distribution protocol for future Abbott test kits, Cepheid test kits, reagents and swabs to public health labs using the [International Reagent Resource](#) (IRR), which was developed by CDC. The prioritization approach is based on how heavily the state relies on the public health laboratory compared to the commercial sector and university laboratories, meaning that rural states are higher up the priority list. Federal sources report that states will each receive 15 of the machines needed to run the tests (each comes with 24 individual tests). There has been little guidance about distribution within the state, so states have discretion to determine priorities. Abbott also continues distributing test kits to current clients. For example, CVS will be purchasing kits to supply its [new drive-through test sites](#) in Georgia, Massachusetts and Rhode Island.
- Mesa Biotech's [Accula SARS-Cov2 Test](#) returns results in 30 minutes and fits in the palm of the hand, allowing for multiple devices to be run concurrently in clinical settings.
- [Cepheid's Xpert Xpress SARS-CoV-2 test](#) returns results in 45 minutes and can be used with either a nasal swab or a nasal wash, which does not require swabs. However, labs have reported difficulty in accessing the tests.

High-throughput tests: These tests require the collection of samples by a health care practitioner or using a new CDC-authorized, self-administered nasal swab approach with oversight by a health care professional (for example, at a drive-through test site). Collected specimens are sent to laboratories with high-throughput platforms (such as [Roche](#) and [ThermoFisher](#)) where the samples are analyzed in large volume. These tests are typically the most accurate (with proper specimen collection); however, they often require additional materials such as swabs, reagents, extraction media, etc. and take 3-6 hours to process. Due to backlogs at the laboratories, results may take one to 10 days for results to be returned. Large diagnostic laboratories report their average processing time is now within a 2- to 4-hour window.

- Newer FDA emergency use authorizations include tests that are quicker to run, fully automatic, and/or test for a panel of respiratory illnesses:
 - [Luminex's NxTAG CoV Extended panel assay](#) can process 96 samples in four hours and tests for the novel coronavirus as well as 20 other respiratory illnesses.
 - The [BioFire COVID-19 test](#) delivers results within an hour and is automated.
 - See full EUA list [here](#).

Serologic testing is used to identify the presence of antibodies to the virus in the bloodstream. Serological tests are not indicated for diagnosis, but will be crucial to the next phase of pandemic response to determine the extent of exposure in a community. [The FDA](#) and virology and immunology experts note additional research and validation of tests is required, and selection of quality tests should be considered for purposes other than surveillance research. On May 4, the [FDA released updated guidance](#) on serology tests which now requires manufacturers producing serology tests to submit an emergency use authorization request to the FDA along with validation data, and FDA has provided specific performance thresholds recommendations for how sensitive and specific the test is to detecting COVID-19. As part of the announcement, the FDA also explained that the National Cancer Institute (NCI) will begin independently validating certain antibody tests, including those that were not the subject of an EUA and those under FDA review. NCI has results for 13 tests which FDA is preparing to share. FDA also released a new [webpage](#) on May 6 that lists the serology tests that have received EUA and information on their accuracy as reported during the EUA process.

- Twelve serologic tests have received EUA from FDA (the first include: [Cellex](#), [Ortho-Clinical Diagnostics, Inc](#), [Chembio Diagnostic Systems, Inc](#)). Several others are awaiting approval.
- CDC also [announced](#) it is developing a serological test for the purpose of determining how much of the U.S. population has been exposed.
- New York and California’s public health labs have developed their own serology tests.

Recent independent reports from the Johns Hopkins Center for Health Security ([report](#)) and the Infectious Disease Society of America ([report](#)) emphasize that, given the lack of validation of current tests and outstanding questions about whether the presence of antibodies indicates protective immunity, serologic testing is currently most appropriately used for surveillance and research and not for diagnosis or staffing decisions or decisions of whether to use PPE. Both reports also highlight important privacy, legal, and ethical considerations of using serologic testing for “immunity passports.” In addition, multiple groups have begun compiling information on performance data and completing their own validation studies.

- FIND Dx, in partnership with the World Health Organization (WHO) is [centralizing](#) the collection of independent diagnostic performance data (including tests that detect nucleic acid, viral antigen, or antibodies). Their dashboard suggests a wide range in performance for serologic tests with most between 50 – 100 percent sensitivity and 80 – 100 percent specificity.
- The Center for Health Security is [publishing](#) manufacturer-reported sensitivity and specificity for all of the serologic tests for which the information can be found that have received EUA from FDA or approval for diagnostic use in other countries. Tests that received EUA from FDA for use in the U.S. range from 90 – 97 percent sensitivity and 95 – 99 percent specificity.
- The COVID Testing Project consists of a team from UCSF, UC Berkeley, Chan Zuckerberg Biohub, and Innovative Genomics Institute. The team is performing [comparisons](#) of commercially available serologic tests (rapid serology tests and ELISA immunoassays). Their reporting includes an evaluation of test performance over time from symptom onset.

At-home tests: The FDA approved the first test for at-home sample collection on Apr 20, by reissuing the EUA for LabCorp’s diagnostic test. Companies that launched at-home testing previously have since stopped selling tests due to FDA intervention. It is anticipated that at-home tests may become an important part of augmenting testing capacity. In the short term, this may take the form of at-home sample collection, which is sent to a laboratory for testing, like the new LabCorp test, however, in the longer-term, there may be tests validated that can produce results at home. Both will require validation and consideration of appropriate sample collection, whether test integrity (and, therefore, accuracy) can be maintained with at-home collection and remain stable during transport to laboratories. An important consideration for any tests that produce results from the home will be how those results are communicated to localities, states and the federal government for public health surveillance.

- A collaborative study by UnitedHealth, Gates Foundation, University of Washington and Quest Diagnostics found that self-administered swabs (taken from the lower part of the nostril) accurately

detected COVID-19 as consistently as clinician-administered swabs (in the back of the nostril). FDA now allows this new method of collecting COVID-19 samples. In the short term, the method reduces the heavy reliance on health care providers to use PPE for testing purposes. In the long-term, it paves the way for at-home testing. The Gates Foundation [is working with](#) the FDA to study home-based, self-administered collection methods.

- Washington state has validated and approved at-home self-swab collection as part of the [SCAN surveillance program](#).

CRISPR-based rapid testing: Researchers from the University of California San Francisco and Mammoth Biosciences [published a paper in Nature](#) describing a new technique to use CRISPR (a DNA cutting and editing technique) to test for COVID-19 in less than an hour, referred to as [DETECTR](#). The test does not require sophisticated machines to use and can be processed in any lab and changes color to indicate a result. · FDA [issued an EUA](#) for the first CRISPR-based diagnostic test to Sherlock BioSciences, Inc. on May 6. Researchers at other institutions are working on similar techniques.

Additional Resources

- [FDA FAQs on COVID-19 Diagnostic Testing](#)
- [FDA updated guidance on serology testing](#)
- [FDA webpage listing serology testing performance](#)
- [CDC Information for Laboratories](#)
- [CDC priority guidance for testing](#)
- [FDA List of COVID-19 Tests with Emergency Use Authorization](#)
- [CDC COVIDView: A Weekly Surveillance Summary of U.S. COVID-19 Activity](#)
- [Harvard Global Health Institute released updated estimates of state testing needs](#)
- [Duke Margolis Center for Health Policy Testing Roadmap](#)
- [The COVID Tracking Project](#)
- [Our World \[Data\]\(https://ourworldindata.org/covid-testingin\)](https://ourworldindata.org/covid-testingin)
- [NGA Roadmap to Recovery: A Public Health Guide for Governors](#)
- White House Testing [Overview](#) and [Blueprint](#)