MEMORANDUM

April 24, 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 provides more comprehensive historical information.

COVID-19 testing is essential to informing clinical care and reducing spread of the virus through a targeted public health approach 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. Experts anticipate additional diagnostic testing options to be widely available in the next several months, supplementing increasing laboratory testing capacity. But lack of widespread access to accurate testing is the greatest limiting factor to moving toward relaxing social distancing restrictions.

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.

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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 ameliorate 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, and the possibility of reliable at-home testing. 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. Serological 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 155,000 people per day (or 0.47 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. A scaled testing approach at the higher end of that range would require easier, accurate sample collection via multiple types of tests (including POC and reliable at-home tests), transportation logistics to rapidly collect and distribute test kits, lab capacity that can handle millions of tests per day, and information systems to electronically transmit results. Western countries further along in the pandemic response are ramping up capacity for mass testing and economic recovery. Germany has tested 20.9/1000 people, Italy is testing 23.6/1000, and Iceland is testing 125.6/1000, compared to approximately 13.5/1000 people in the U.S. despite cases far exceeding numbers in other countries. Higher levels of testing in South Korea, Taiwan and Singapore have been a critical element in their ability to control the spread of the disease.

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 to ensure national access to testing continues to be an option.
  - On April 23 the House passed a $484 stimulus bill that was passed by the Senate on April 21 and is expected to be signed by the President on the 24th. The bill includes $25 billion for testing, $11 billion$^1$ 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 goals, needs, estimates of capacity, and how resources will be used. The other $11 billion would go to the CDC and 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.

- **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.
  - California and Connecticut each formed state task forces to lead the development, sourcing and distribution of tests.

- **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

$^1$ 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 Centers for Disease Control and Prevention; $1.8 billion for the National Institutes of Health, 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 Food and Drug Administration; $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 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.
and test components in shortage, including taking advantage of self-administered nasal swab collection per guidance from the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (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, Governor Hogan announced on Apr 20 that Maryland received 500,000 test kits from South Korea.
- Governor 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 Flanagan emphasized that testing would be especially crucial for vulnerable populations include those living or working in congregate care settings or experiencing homelessness, communities of color and American Indians, and critical workers.

- **Work with state health officials to monitor test performance to inform testing policies.** The need for rapid escalation of testing beginning in February led FDA to issue guidance on diagnostic test development and analysis in order 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 negative results may result from timing of specimen collection (too early or late in infection), improper sample collection, or issues in storage and transport. False negative results are potentially problematic in a true assessment of infection. 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.

- **Federal distribution of kits and equipment.** On April 9 the federal government began a distribution protocol for diagnostic platforms and supplies including Abbott and Cepheid POC test kits, reagents and swabs to public health labs using the International Reagent Resource (IRR) which was developed by the CDC. The prioritization approach is based on how heavily the state relies on the public health laboratory compared with the commercial sector and university laboratories. While this will represent an increase in access for public health labs, the supply chain remains a challenge and demand will not be met in the short term.

During the April 20 Coronavirus Task Force press briefing it was announced that the administration provided governors and state health officials with specific information by state about available laboratories and location of laboratory equipment for diagnostic testing. The administration also enlisted a team from Walter Reed to call laboratories across the country to identify barriers to testing at capacity which may include access to swabs and reagents, and necessary data feeds for testing to be
useful to clinicians and public health. Vice President Pence also noted that federal laboratories and Department of Defense laboratories would be made available to states as needed for testing capacity. The administration will also provide technical assistance to states to ensure all of the machines are brought online and that states can set up a recommended ‘hub and spoke’ model to coordinate testing in the state. Additional details are forthcoming, including how this effort will coordinate with existing state efforts.

- **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. The major manufacturers, Copan and Puritan, are able to manufacture about 6 million swabs per week. 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 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.
  - On April 19, President Trump announced that a large manufacturer of Q-tips in Ohio will soon convert to producing 10 million swabs per month for testing and that the administration is planning to use Title 3 of the DPA to help the largest manufacturer of swabs in the northeast build four new production lines to produce 20 million more test swabs per month.

- **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 that have core lab capacity are better positioned with equipment, space, human 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 also may be necessary 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 authorized by the FDA on April 13).
In addition, at-home testing approaches are hailed to increase access to testing and reduce the need for health care worker oversight, and associated PPE. The first at-home test, from LabCorp received EUA 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 depending on the phase of the pandemic and testing capacity and therefore may differ by state.

- Current federal guidance includes the following priority groups:
  - **Priority 1**: Hospitalized patients; symptomatic healthcare workers
  - **Priority 2**: Patients with symptoms in long-term care facilities, who are 65 years of age or older, or who have underlying conditions, and first responders with symptoms
  - **Priority 3**: Critical infrastructure workers with symptoms, other individuals with symptoms, healthcare workers and first responders without symptoms, and individuals with mild symptoms in communities with high COVID-19 hospitalizations
  - **Non-priority**: Individuals without symptoms

- The Association of State and Territorial Health Officials (ASTHO) also released their own guidance on prioritization [here](#).

- Many states have implemented their own prioritization protocols based on their state’s phase of response and access to testing resources.
  - California updated their priority testing guidance to include individuals identified from contact tracing and individuals in high risk settings in the first priority group and screening of asymptomatic residents of congregate living and healthcare workers in the second priority group. A fourth priority group includes community-based testing and surveillance of low-risk and asymptomatic people. The state plans to review priority groups regularly.
  - Wisconsin recently 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.
  - Colorado elevated “critical infrastructure employees with symptoms” to tier 2 for testing after infections popped up at critical electricity facilities.
  - Utah recommended that all individuals with fever or signs and symptoms of lower respiratory illness are tested for COVID-19.

- 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 for multiple reasons. 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. 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 campus grounds for testing. The Connecticut Department of Health dedicated two full-time regulatory staff to partner closely 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 that the state in partnership with the National Guard will operate 15 drive-through testing sites for anyone regardless of symptoms for 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.
- Walgreens announced its 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.

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 its 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” testing sites to address the needs of residents without access to a car.

- 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.
- As of April 10, New York City is offering walk-in testing at health care centers in the South Bronx, Jamaica, Queens and Brownsville, Brooklyn.
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.

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.

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. Serological testing, which tests for immune response rather than presence of the virus, is being employed in many of these studies. (See
CDC and no/ire and provide,000 volunteers. to work (individuals critical to understand the current pandemic and the agency

Appendix for more details.) While a few tests are awaiting FDA approval, three have been approved to date and 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.

- 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. In addition, 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

- 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.

- 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.

- New York Governor Cuomo announced during his press briefing on April 23 that preliminary results of their serology study of 3,000 samples from 19 counties indicated a 13.9% infection rate for the state. Long Island and New York City had the highest rates of infection, while the rest of the state was closer to 3.6%. The racial and ethnic breakdown was also included with Latino/Hispanic and Multi/None/Other around 23%, Black at 22%, Asian at 12%, and White at 9%. 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 serological study. Preliminary results indicate that the number of true infections may be 50-85 fold higher than confirmed cases.

- Miami-Dade County is beginning 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 NGÀ’s memo summarizing the study.

- Ohio is starting a random sample to test for antibodies among 100 asymptomatic people.

- 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.

- Arizona Governor Ducey announced a partnership with the University of Arizona to provide serological testing to 250,000 healthcare professionals. The University is waiting on an EUA for the test.

- 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.

Some localities and other countries have begun exploring testing protocols that could be used to identify individuals with immunity (using antibody testing) or to identify individuals as healthy and able to return to work (through diagnostic testing). The FDA and many experts note that both serological 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 someone is clear of the virus.

- **Diagnostic Testing:**
  - 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.
  - Amazon announced that 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 to do so through assembling equipment to build a laboratory and are moving scientists, managers, procurement officers, and software engineers to be dedicated to the initiative.

- **Serologic Testing:**
  - 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.
  - New York is developing its own serology test and is seeking an emergency use authorization (EUA) from FDA. The state will be able to produce 2,000 tests per day, but Governor Andrew Cuomo called on President Trump to use the defense production act (DPA) to manufacture enough serological testing to allow New Yorkers and others to go back to work.
  - German, Italian and British politicians 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.

In addition, the federal government and the commercial sector have indicated that expanded use of telemthermographic systems for taking body temperature measurements may be helpful in workplaces, airports, etc.

- On April 16 FDA issued guidance intended to expand the availability of telemthermographic 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.
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.

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.

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

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Appendix

Overview of Current Type of Testing and New Notable Tests

**Rapid Point of Care Tests:** Recent emergency use authorizations (EUAs) 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 next couple of 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 the swabs. However, labs have reported difficulty in accessing the tests.

**High-throughput tests:** These are tests that require the collection of samples by a health care practitioner or using new CDC authorized self-administered nasal swab approach with oversight of 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 that their average processing time is now within a 2-4 hour window.

- **Newer FDA emergency use authorizations (EUAs) 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](#).

**Serological 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
that additional research and validation of tests is required, and selection of quality tests should be considered for purposes other than surveillance research. FDA guidance is that they will not object to the development and use of serological testing without an EUA during the public health emergency. However, the FDA recommends caution as these tests have not been validated by the FDA and some of them are aggressively marketed as POC or at-home diagnostic tests. Reports of unreliable tests are increasing (e.g. in Laredo, Texas and in the U.K.). FDA has received notification of more than 80 such tests in development or use.

- Three serologic tests have received EUA from FDA (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.

**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 early 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 at 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 DECTR. The test does not require sophisticated machines to use and can be processed in any lab and changes color to indicate a result. The test will be submitted to FDA for an EUA. Researchers at other institutions are working on similar techniques.

**Additional Resources**

- FDA FAQs on COVID-19 Diagnostic Testing
- CDC Information for Laboratories
- FDA List of COVID-19 Tests with Emergency Use Authorization
- CDC COVIDView: A Weekly Surveillance Summary of U.S. COVID-19 Activity
- Duke Margolis Center for Health Policy Testing Roadmap
- The COVID Tracking Project
- NGA Roadmap to Recovery: A Public Health Guide for Governors