
MEMORANDUM

March 26, 2020

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

As governors continue to lead in preventing the spread and mitigating the negative consequences of COVID-19, significant limitations on testing supplies and laboratory testing capacity must be considered in short-term planning. Test availability and laboratory capacity to analyze specimens are increasing, but supply chain pressures, especially regarding seriously limited access to reagents, and other test equipment (e.g., swabs and viral transport media) and severe shortages of personal protective equipment (PPE) (e.g., N95 respirators, masks, gowns, gloves) are significantly limiting population-level testing approaches. Accordingly, many state and local health departments are imposing criteria on who may be tested, prioritizing symptomatic people who are also in the front line (such as health care workers, first responders) or high risk categories (hospital patients, older adults, especially in long term care, and people with underlying conditions) until capacity increases. Governors are also working with their senior advisors and commercial partners to supplement a modest supply of reagents, test equipment and PPE from federal sources with their own strategies to acquire or produce these supplies. But given global shortages and unclear timetable from the federal government, a lag is inevitable. Therefore, current strategy may include working closely with relevant cabinet officials to continue to manage expectations through public communications and to begin developing medically and ethically grounded contingency plans for limited supplies of tests and other medical equipment.

This memo addresses approaches governors may take to increase access to testing such as (i) expanding access to tests and laboratory capacity to process the tests, (ii) assertively working with the federal government and commercial suppliers to obtain test equipment and PPE; (iii) expanding drive-through testing options, and (iv) providing consistent testing guidance for providers and consumers in the context of limited resources.

I. Expand access to tests and laboratory capacity to process tests through public and private laboratories.

Governors may expand testing through public and private laboratories with new flexibility from the U.S. Food and Drug Administration (FDA). On March 16 (largely in response to Governor Cuomo's [requests](#)), FDA Commissioner Hahn [announced](#) that states can set up their own system in which they take responsibility for authorizing such tests and the laboratories will not need to engage with the FDA to conduct COVID-19 testing. The updated guidance also expands the types of labs that can conduct testing and provides recommendations for test developers who are interested in developing a test. According to state health officials and health system leadership, the flexibility is welcome but the validation process is challenged by difficulty obtaining needed reagents generally and requirements to use the exact CDC platform in experiments to obtain Emergency Use Authorizations (EUAs) as outlined in the FDA guidance. Limited testing capacity has also resulted in specimen processing backlogs in some states that

are scrambling to preserve specimens (e.g., building freezer and shipping capacity) and to partner with national labs to help process the backlog.

On March 22, FDA updated its [guidance](#) to COVID-19 testing procedures to allow test recipients to conduct their own swab, making the process easier, more comfortable for patients and to help limit the amount of PPE used during testing. The guidance clarified that collection of samples at home or locations other than designated collection sites staffed with healthcare providers is currently not recommended due to concerns with specimen transport, and appropriate collection materials. This may change as technology advances (e.g., many laboratories and commercial partners are experimenting with additional swab options to increase supply that also preserves specimen integrity and there is the possibility of in-home collection).

To accelerate the availability of tests through commercial laboratories, the Center for Disease Control and Prevention (CDC) granted “right of reference” to data in their own emergency use application. To date, the FDA has [authorized](#) the emergency use of diagnostic tests for detection and diagnosis of individuals suspected of COVID-19 by their health care providers to the following entities:

- Wadsworth Center, New York State Department of Health ([3-10-20](#))
- Roche Molecular Systems, Inc. ([3-12-20](#))
- Thermo Fisher Scientific Inc. ([3-13-20](#))
- Hologic, Inc. ([3-16-20](#))
- Laboratory Corporation of America (LabCorp) ([3-16-20](#))
- Quidel Corporation ([3-17-20](#))
- Quest Diagnostics Infectious Disease, Inc. ([3-17-20](#))
- Abbott Molecular ([3-18-20](#))
- DiaSorin Molecular LLC ([3-19-20](#))
- GenMark Diagnostics, Inc. ([3-19-20](#))
- Primerdesign Ltd ([3-20-20](#))
- Cepheid ([3-21-20](#))
- BioFire Defense LLC ([3-23-20](#))
- Mesa Biotech ([3-23-20](#))

FDA has given emergency authorization to two point-of-care COVID-19 diagnostic tests (included in the list above) manufactured by Cepheid, whose test provides results within hours and Mesa Biotech, whose test produces results in 30 minutes.

At the time of this memo, commercial partners report distribution of hundreds of thousands of tests to hospitals and laboratories with the instrumentation in place for high volume testing and that distribution of tests will increase significantly going forward. Some also report that individual laboratory productivity may reach a limit based on the number of machines required to analyze specimens (either due to supply or competing demands for routine use). The latter may be a short-lived challenge, however, with the availability of point of care testing noted above. Some states have reported challenges with rapid data sharing from laboratories beyond direct report from the department of health (e.g., directly to state Health Information Exchanges).

The following are examples of strategies governors have pursued to increase access to COVID-19 testing and laboratory capacity in the context of currently limited supply:



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- In New York, Governor Cuomo [authorized](#) all 28 public and private laboratories in the state to begin manual and automated tests for COVID-19, significantly increasing capacity that had previously been limited to two state public health laboratories.
- Oregon and Indiana announced new public-private partnerships to accelerate access to testing.
 - Oregon has [contracted](#) with Quest Diagnostics (Quest) to obtain 20,000 test kits and Quest will deliver 5,000 kits immediately. Governor Brown has indicated that Oregon has already begun receiving test results from LabCorp and the state will be [rolling out](#) their own testing through additional public and private partnerships.
 - Governor Holcomb and the Indiana State Department of Health (ISDH) [announced a new partnership](#) with Eli Lilly (Lilly) and Company to accelerate COVID-19 testing in Indiana. Lilly will use its research laboratories to analyze samples taken in Indiana health care facilities, including nursing homes and emergency rooms, to increase the state’s ability to conduct testing for COVID-19. As Lilly’s testing capacity expands, Lilly and ISDH will work together to increase testing.
 - In an effort to address reagent shortage and relieve a backlog of tests, Maine is purchasing a second high-capacity platform to avoid potential vulnerability to a “single source of failure” that may be associated with one platform/one reagent during shortages.

II. Work with your COVID-19 response lead, state health official and/or emergency manager to acquire testing equipment and PPE needed (generally and at testing sites) from the federal government and other sources.

Resources through the federal government, including the Strategic National Stockpile are being sent out in a phased manner but current supplies will only meet a fraction of the need. In response to national and global shortage of PPE and medical equipment, governors are assertively calling for additional federal support and pursuing their own channels to obtain essential equipment. President Trump invoked the Defense Production Act (See NGA memo [here](#) for additional information) and is currently working with the business community to ramp up production on a voluntary basis.

Even as production ramps up, availability of equipment will lag behind the need. Therefore, governors may consider the following strategies to address test equipment and PPE shortages:

- **Continue making time-phased, data informed requests for PPE and medical supplies from the United States Health and Human Services Assistant Secretary for Preparedness and Response (ASPR) from the strategic national stockpile (SNS).**

The week of March 16, U.S. Health and Human Services (HHS) officials noted in a telephone briefing that additional PPE are being sent to states. They indicated the importance of notification and clearly defined demand from states to inform their approach. As of that briefing, ASPR’s approach to handling what is currently in the stockpile for PPE (including N95 respirators, face shields, gowns, gloves) includes: 25% of inventory allocated on a proportional basis to all jurisdictions; 25% will be held back for targeted high intensity hot spots; and 50% will serve as strategic reserve to respond to trends and needs across the country and to supply the community-



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based testing initiative that is being operated through the federal public-private partnership (described below). In addition, ASPR is in the process of distributing swab kits to state departments of health but amounts and timetable is unknown. Early reports from state health officials on receipt of PPE indicate that inventory reaching those states is far short of requests, with one state noting that 14% of the amount requested had been received through the initial distribution.

- **Require health care providers to postpone elective surgeries and non-essential medical and dental procedures and limit staff in surgery suites to essential staff in order to conserve PPE.**
 - **In order to preserve PPE, the federal government has issued guidance and several states have moved to postpone elective surgeries and procedures and limit staff involved to those that are essential to conducting the surgery or procedure.**
 - **Centers for Medicare & Medicaid Recommendations to Cancel Adult Elective and Non-Essential Medical, Surgical and Dental Procedures:** CMS released recommendations dated March 18 to delay non-essential procedures in an effort to preserve personal protective equipment (PPE), beds, and ventilators for facilities as well as to free up health care workers to treat patients with COVID-19. The recommendations provide a framework for hospitals and clinicians to implement immediately to determine and identify non-essential and elective procedures. The recommendations and guidelines can be found [here](#).
 - **State actions:** Governors from several states issued orders halting elective and non-essential procedures to ensure personal protective equipment (PPE) is available where it is most needed and to maintain the capacity for hospitals and providers to continue offering vital services. With the shortage and current rationing of PPE including reuse and prioritized distribution, limiting elective procedures can minimize the risk of transmission of the virus from asymptomatic patients to others in the waiting room and surgery teams. States including [Arizona](#), [Colorado](#), [Iowa](#), [Massachusetts](#), [Minnesota](#), [Ohio](#), [Oregon](#), and [Washington](#) have taken actions to restrict elective and non-essential medical, surgical and dental procedures.
- **Consider partnering with the U.S. military for distribution of testing supplies and PPE.** U.S. Department of Defense announced that the Pentagon will give 5 million respirator masks and up to 2,000 deployable ventilators to HHS for civilian response to COVID-19. In addition, on [March 18](#), Tennessee's Air National Guard the US Air Force flew 500,000 swab and specimen collection materials to Tennessee from Italy to distribute across the country. Governors may request Department of Defense support via the Stafford Act and the Federal Emergency Management Agency (FEMA). These requests can be made by a state's emergency manager to their respective FEMA Regional Administrator.
- **Using the National Guard:** The majority of the states and territories have activated their respective National Guard to help support efforts to combat COVID-19. The National Guard



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response missions in the state include: using civil support teams for personal protective equipment training and sample collection; response planning; supporting medical testing facilities; providing response liaisons and support to state Emergency Operations Centers; supporting healthcare professionals in assessments and transportation; logistical support; assisting with disinfecting and cleaning of common public spaces and collecting and delivering samples.

- **Title 32 Activation:** Governors may request from the federal government the authority to activate their National Guard on Title 32 United State Code orders. Under this authority, the National Guard remains under the command and control of the governor, but guard members receive federal pay and benefits. On March 22, the president authorized this authority via [Executive Order](#) for California, New York and Washington to help provide state flexibility in responding to COVID-19.
- **Dual Status Commander:** Should the Department of Defense provide Title 10 forces and resources to a state, a governor could request and ensure that the Department of Defense appoints a [Dual Status Commander](#), specifically a trained and certified National Guard member in their respective state. A Dual Status Commander will ensure a clear chain of command of military forces within the states as well as unity of military forces. The appointment of a Dual Status Commander must be agreed to by both the governor and the president.
- **Simplify the process for donating and transporting PPE and supplies.** Several states and localities are employing creative ways to address supply chain pressures, some states including [Rhode Island](#) and [Connecticut](#) have created an online portal so organizations can donate supplies and personal protective equipment. Connecticut is leveraging the United Way 2-1-1 platform for this purpose. Tennessee Governor Lee issued an [executive order](#) suspending requirements related to transporting medical supplies in the case of vehicles participating in the response to COVID-19 under certain conditions.
- **Pursue partnerships with the business community directly or through the federal government.** For example, Governor Cuomo of New York reached out directly to the business community to purchase any PPE products that are not currently being used for essential services and to begin manufacturing PPE with funding from the state. In addition, other federal, state and commercial efforts are ramping up production. For example:
 - Tim Cook, CEO of **Apple** [tweeted](#) on March 21 that Apple will donate millions of masks for health professionals in the U.S. and Europe.
 - Amazon [pledged](#) \$20 million to accelerate diagnostics, research and testing for COVID-19 through its AWS Diagnostic Development Initiative.

The Families First Coronavirus Response Act, H.R. 6201 provided liability protection for N95 mask manufacturers to ramp up production of N95 masks by using production lines not certified by the FDA to equip health care workers during this critical period. Manufacturers such as 3M, Honeywell, Modex, Prestige Ameritech, Owens & Minor all [estimated](#) that they could ramp up production significantly as a result.

- For example, Honeywell [announced](#) on March 23, that they will ramp up production in its Smithfield, Rhode Island location to make millions of N95 masks which will be delivered



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to HHS, and have increased production of masks globally.

- Clothing companies, such as Hanes [announced](#) that they will be retrofitting some of their facilities to produce medical masks (general use masks rather than N95 masks).

III. Establish community-based drive-through and walk-up testing stations or consider mobile testing options to alleviate pressure on emergency departments and urgent care centers.

- **Build partnerships with health systems and corporate partners to stand up drive-through testing sites.** Some states have taken the lead on establishing drive-through testing locations, which are opening across the country. Other states are considering mobile testing options in partnership with community paramedicine (as testing capacity allows) to reach affected individuals and to minimize miscommunication about wide availability of testing that is accompanying drive-through testing locations. Notably, some have observed that drive through testing allows for conservation of PPE. Examples of drive-through approaches include:
 - **New York** has opened a number of drive-through or mobile testing locations beginning in New Rochelle (serving all parts of Westchester County) – among the hardest hit areas in the country. As part of a [state initiative](#) to replicate this model in a number of other locations, centers have been stood up in Nassau County and Staten Island (the first facility in New York City). Sample public guidance and communications about eligibility and protocols can be found [here](#).
 - **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.
 - **Colorado** has a state-run testing center operated through the [Colorado](#) Department of Public Health & Environment.
 - **Commercial partners** have also stepped up to establish drive-through testing.
 - On March 19, **CVS** opened its first drive-up testing location in Worcester County, Massachusetts for testing of first responders and health care workers. Walgreens, Walmart and Target [pledged](#) at a White House press conference to open locations as well.
 - On March 22, Walmart, in partnership with the federal public-private initiative [opened](#) two testing sites in supercenter parking lots in Chicago.

The Association of State and Territorial Health Officials working closely with state health officials [have compiled](#) a list of 16 key considerations for standing up these sites.

- **Work proactively with HHS to stand up drive-through testing sites through the new federal public-private partnership initiative (now commonly referred to as community-based**



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testing sites or CBTS). Work with state COVID-19 task force, health officials and emergency management leads to determine geographic needs and to make site requests. The first federal sites were stood up the week of March 16 including in California, Colorado, Massachusetts, New Jersey, New York, Pennsylvania, and Texas with additional sites in the queue. **NOTE:** Early state observations suggest that clear plans to ensure state electronic receipt of testing data is essential to their own surveillance and resource targeting efforts.

Details provided by HHS leadership on the drive-through test initiative include:

- This is a federal public-private partnership intended to supplement state and local efforts – beginning with a few states.
- Sites will arrive as Points of Distribution (PODs) and will be staffed by local health departments.
- The Public Health Service Commission Corps will be deployed to supplement workforce gaps at federal/state partnership sites (These sites will have at least four officers with some variability based on request – to supplement existing workforce).
 - States should assess local health care workforce capacity and submit requests for personnel support from the Public Health Service Commission Corps.
- Mobile sites are expected to process 2,000 – 4,000 tests per day (once fully implemented).
- To meet demand, testing sites will prioritize the following individuals for testing: first responders, health care facility workers (especially those who have come into contact with affected individuals) and then will open to people 65 years-old and older adults who show visible symptoms.

IV. Use a public health approach to prioritizing testing while capacity is limited and communicate a consistent message to the public about when to seek testing

Across the states, there is differing understanding from providers and the general public about where and when to get tested. Both groups would benefit from consistent messaging from governors and their state health officials about the triggering criteria for when to seek testing and who may get tested at locations where testing is available. As of the date of this memo, the White House Coronavirus Task Force, public health and infectious disease experts have clearly communicated that people who are not symptomatic should not seek testing. The recommendation stems from availability of test capacity coupled with managing the scarce supply of PPE, which is also needed to protect those conducting tests. While testing equipment and PPE are in short supply, these experts recommend that people with no symptoms do not seek testing and that testing is prioritized for the most at risk. Recommendations vary somewhat and may be more or less inclusive based on testing availability in a specific region.

On March 23, HHS issued the following guidance strongly recommending states and clinical laboratories utilize in developing strategies to prioritize COVID-19 testing in their communities:

- Priority 1 Testing for COVID-19
 - Hospitalized patients
 - Healthcare facility workers with symptoms
- Priority 2 Testing for COVID-19
 - Patients in long-term care facilities with symptoms



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- Patients over age 65 years with symptoms
- Patients with underlying conditions with symptoms
- First responders with symptoms
- Priority 3 Testing for COVID-19
 - Critical infrastructure workers with symptoms
 - Individuals who do not meet any of the above categories with symptoms
 - Healthcare facility workers and first responders
 - Individuals with mild symptoms in communities experiencing high numbers of COVID-19 hospitalizations
- Non-Priority
 - Individuals without symptoms

On March 20, the Association of State and Territorial Health Officials, Association of Public Health Laboratories, and Council of State and Territorial Epidemiologists also [issued](#) policy recommendations regarding testing prioritization for COVID-19 that differ from HHS guidelines indicating that priority guidelines vary somewhat based on the source and also vary across jurisdictions.

Health officials in states, such as [Ohio](#), and centers of the hardest hit areas, such as [New York City](#) and [Los Angeles](#) have shifted testing strategy from case containment to slowing disease transmission and averting excessive morbidity and mortality in what some are referring to as the new phase of pandemic response. Experts [note](#) that this approach may slow the rate at which people get the virus, extending the epidemic but the peak of mortality and morbidity doesn't go as high (i.e., flattening the curve), and that thoughtfully transitioning to a mass screening and case-based interventions (in which resources are targeted toward locating and quickly isolating affected individuals) should follow when the epidemic curve comes down and resources allow.

Given the different messages, consistent and clear information from governors and their health leaders to providers and consumers is needed. For example, the Ohio Department of Health guidance around testing includes [clear messaging](#) for people concerned about not being able to access tests.

Note – this memo was prepared with information as of March 25. As this is a fast-evolving situation, we anticipate that there will be more federal and state actions related to testing. NGA will continue to monitor these developments and provide updates as needed. Included below is a suite of resources to assist with testing implementation. States are encouraged to continually monitor newly issued guidance detailing any recently approved diagnostics and target populations for testing from HHS, FDA, and CDC.

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

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Federal Resources

- [CDC Testing Guidance for Health Professionals link](#)
- [CDC FAQ for Diagnostic Tools and Virus link](#)



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- [CMS Guidance for Providers on COVID-19 Test Pricing](#) [link](#)
- [FDA COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders](#) [link](#)
- [FDA FAQs on Diagnostic Testing for SARS-CoV-2](#) [link](#)

Other Resources

- [APHL COVID-19 Response](#) [link](#)
- [ASTHO COVID-19 Testing Prioritization Recommendations](#) [link](#)



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