

ACHIEVING  
WIDESPREAD  
AVAILABILITY OF  
TIMELY AND EFFICIENT  
COVID-19 TESTING

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## **Managing the COVID-19 Epidemic – Beyond the Initial Response**

Policy Roadmap

*Current as of March 26, 2020*

This Duke-Margolis resource on COVID-19 response policies is intended to inform and help guide policy makers addressing the evolving COVID-19 pandemic in the United States and around the globe, and will be updated as the pandemic and response capabilities change over time.

It contains recommendations for a U.S. Federal response as well as steps and resources for stakeholders across the health care ecosystem. We will add further resources to address a range of related, critical policy challenges.

We thank our many collaborators, co-authors, and reviewers who have contributed significant expertise and guidance on these rapidly evolving issues. Please reach out to us with additional suggestions for resources and effective policies at [dukemargolis@duke.edu](mailto:dukemargolis@duke.edu) - we welcome your input

### **Achieving Widespread Availability of Timely and Efficient COVID-19 Testing**

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Efficient, reliable, widely deployed diagnostic tests are critical to our ongoing response to the current COVID-19 epidemic, and our ability to prevent future large outbreaks or epidemic spread of this disease.

In the near term, working out large-scale diagnostic testing using [polymerase chain reaction \(PCR\)](#) test capabilities and [point-of-care \(POC\) tests](#) that are beginning to come online is key to the COVID-19 response. While testing capabilities are now scaling up, challenges remain. A smooth pathway, from identifying patients who need testing, to administering the test, to timely analysis and communication test results, is not yet reliably available across the country. We need to ensure an adequate surge supply chains for swabs, pipettes, reagents and other needed materials for testing. We need to identify an adequate supply of safe testing facilities in the short term, such as drive-throughs, pop-ups, or other dedicated spaces that do not cause disruptions to health care capacity when patients test positive. And we need to solve logistical challenges, such as identifying priority patients for testing, scheduling them in an orderly way, and obtaining and sharing timely test results for appropriate treatment and public health monitoring. A related

immediate issue is assuring adequate supply of personal protective equipment for medical personnel.

These are all critical tasks for responding to the current outbreak that deserve the intense immediate attention they are receiving.

**Building on this immediate response, we need to develop a massive testing capability – distributed nationwide – that allows for easy routine testing of all individuals appropriate for COVID-19 testing for the duration of the COVID-19 threat.** This will include a robust surveillance system designed to detect small pockets of community spread before they turn into large outbreaks. It should also include obtaining widespread serological test results, available through routine blood tests, to accurately gauge the background rates of immunity in the population to inform public health decision making. Such diagnostic testing capacity is the foundation of widespread surveillance that will eventually turn COVID-19 into a more manageable threat, in advance of having a safe and effective vaccine.

The investments we make in expanding our diagnostic capacity in the setting of the current epidemic outbreak will serve us well toward these longer-term goals. They will lay the testing foundation for the surveillance screening system that we will need to have in place after the immediate epidemic threat starts to subside. Broad availability of timely diagnostic testing for appropriate individuals is a complement for a national testing capacity (using well-established serologic testing) to enable a clearer understanding of exposures and trends in each region of the country and to target public health response based on local risk.

To reduce challenges in access to these testing capabilities, further innovation in COVID-19 diagnostics and tools are needed, including greater availability of PCR testing, testing innovations to add to POC diagnostic testing capacity, as well as the development of validated self-testing capabilities such as “self-swabs” and home testing that would reduce the need for dedicated facilities, like drive-through testing sites, that now provide needed access but consume substantial masks, gloves, and other personal protective equipment.

As [two of us wrote recently](#), diagnostic test innovation to enable broad, timely access to appropriate testing is one of a set of key public health objectives that will enable a significant and sustained reduction in the intensive physical isolation measures being implemented now, with their associated impact on the well-being of Americans and on economic activity. This surveillance screening will be critical to our ability to transition from the broad population-based mitigation strategies that we’re now employing to break the viral transmission (school closures, stay at home orders) to more case-based interventions that target public health tools towards better understood, more targeted risks.

Here, we describe steps to achieve this key objective, building on very recent progress including [FDA emergency guidance development](#) and [initiatives to improve ease of testing](#). This requires further increases and more efficient integration of existing PCR testing capacity, the development of substantial POC rapid testing capabilities, and reliable supply chains. It also includes progress toward more convenient and less disruptive testing methods. To achieve maximum progress, we

have previously proposed the creation of an Innovation Task Force to augment current efforts, with senior Administration leadership including FDA's Center for Devices and Radiological Health (CDRH), supported by the Centers for Disease Control and Prevention (CDC), Biomedical Advanced Research and Development Authority (BARDA), supply chain and deployment initiatives coordinated through the Federal Emergency Management Agency and the White House COVID-19 Task Force, working with the laboratory testing industry, outside experts, and providers. Regardless of whether such a task force is formally created, or if this major diagnostic testing initiative is undertaken through existing structures, **the set of steps we describe here are needed to advance the availability of the testing capacity required for effective management of COVID-19 in the weeks and months ahead.**

#### *Accelerate Diagnostics Innovation to Augment Testing Capacity*

The FDA and industry [have taken steps](#) to move rapid, common-platform COVID-19 PCR tests and an initial POC test through regulatory approval. **To enhance this support for accelerating the development of validated POC testing capacity, the approaches used in CDRH's [Rapid Influenza Diagnostic Test \(RIDT\)](#) development model could be expanded to grant [Emergency Use Authorization \(EUA\)](#) for additional POC COVID-19 tests.** Such influenza tests now provide results in 15 minutes on commonly available POC testing platforms, and are widely available in medical offices, urgent care centers, and other community sites today.

In particular, and similar to the RIDT model, FDA could set a level of minimum performance standards that the POC tests would be required to achieve, including on test sensitivity and specificity. CDC, outside experts, and the device manufacturers should have input into developing the standards to make sure they meet the public health needs and are technologically feasible. Given concerns about false-negative results and individuals who are infected but asymptomatic, the performance expectations would likely need to be higher than for RIDTs. FDA's recent emergency guidance could streamline the need for individual premarket review of each test by establishing performance expectations, developing common validation protocols, making available model instructions for use, and requiring manufacturers who participate in this program to report post-market test performance and any necessary test modifications. To ensure widespread access to POC testing, the supply chain needs of the medical offices and care centers expected to run the tests should also be considered by HHS and FEMA at the time that the manufacturers are seeking their EUA.

In addition to expanding the availability of PCR-based diagnostic tests, we must support labs and manufacturers who can provide serum antibody testing (or develop more convenient versions of these tests) to evaluate immunity for patients who might not have had access to the initial diagnostic tests because early capacity has been so constrained. **Understanding the patterns of exposure, and how much immunity is in a local population, is critical to public health decision-making.** Knowing that a community has a high background level of immunity may inform decisions to implement less stringent mitigation steps in the face of a small outbreak versus a similar community with very low levels of prior exposure and immunity, where more stringent steps could be taken in the setting of a similarly sized level of spread.

*Accelerate Production and Availability of New Diagnostics*

Especially for innovative laboratories and smaller companies manufacturing new types of tests, approval does not necessarily translate rapidly into broad availability of the test. Manufacturers of new tests that meet the minimum standards need assurance and potentially assistance in investing to achieve large-scale manufacturing rapidly. We propose three steps to support such production.

**First, at the time a test is seeking emergency authorization, HHS and FEMA can request information regarding the manufacturer’s production capacity, to evaluate whether how much it matters for meeting national objectives for widespread patient access if approved, and to consider what financial or logistical support might be needed to expand access.** This requires an ongoing government capacity to track current and expected capacity by region with expected needs for the national surveillance strategy.

**Second, tracking the adequacy of current and future supply versus testing need would be used to assure adequate production to manage the current surge as well as to be prepared in advance to manage any future outbreaks.** The task force should assure that information on current and needed capacity is widely available, to help payers and providers make the investments needed to close regional and national gaps in capacity as quickly as possible. Different facilities use different test platforms, and overall platform capacity may be short of projected testing needs. The task force would work with manufacturers and providers gaps to eliminate gaps in such additional diagnostic test supply and availability.

**Third, the task force should work with CMS and other insurers to assure a clear and predictable pathway for coverage and payment of innovative tests that fill gaps and address unmet needs.** Rapid CMS action related to coding, coverage, and payment for current PCR tests has prevented those issues from causing delays in production and access. As promising tests with new capabilities are developed, for example potential home-based tests as described below, a timely preapproval process for providing clarity about coverage, coding, and payment may be needed.

**Fourth, the task force should encourage timely production of sufficient diagnostic tests by determining the need for advance purchases by public payers (e.g., Medicare) and potentially by private insurers for tests that meet the minimum standards to assure preparedness.** CMS could lead the development of a template that private insurers could potentially follow. BARDA could augment these steps through its existing mechanisms for providing advance support for manufacturing capacity, as well as [purchases for a reserve stockpile](#) of test capacity and materials (described below) in the event of a more significant outbreak. Preference could be given for critical elements of the supply chain that are manufactured in the U.S., which can help ensure future supply for the domestic market in the setting of rising global demand for these components. Knowing that tests and components will be reimbursed for a minimum level of testing capacity would encourage providers to invest in adequate testing capacity, especially in areas with inadequate capacity now.

This is not just a short-term activity. CMS, BARDA, and private payers should also assure that testing supply is adequate to sustain an effective surveillance system throughout the country for

as long as COVID-19 outbreaks remain a threat; because a future outbreak that is not detected quickly could cause broad harm to the public, individual payers and providers may not sustain adequate local capacity to detect such outbreaks quickly without public support. Effective containment of the current epidemic is not sufficient; adequate production and local testing capacity must be maintained for the future.

#### *Assure Adequate Supply of Required Test Materials*

Alongside additional test authorization and availability, adequate production is also needed now and in the future for the laboratory supplies that are required to conduct COVID-19 tests. The test kits that are shipped to laboratories must be run on analyzers and with testing supplies like swabs needed by the testing facilities, and the reagents and preparation materials needed by laboratories to run the test kits, that must be purchased separately.

**Manufacturers supported by this initiative would need to specify in advance the expected requirements for laboratory materials needed to run the test but not provided by the manufacturer.** Federal collaborations with laboratories, manufacturers, potential manufacturers, and public health experts are already working to improve the supply of such materials. These initiatives include private-sector collaborations to obtain needed capacity (e.g., through the [Business Roundtable](#) and other groups), reinforced by the Federal government's emergency production and procurement authorities for products that are in short supply (e.g., [Defense Production Act](#) and public health emergency funds). This tracking capacity is being refined, and would be integrated with planning for the materials needed but not included in the new diagnostic tests. The large commercial and academic laboratories need to be active participants in establishing the supply chain needs up front. This part of the diagnostic testing initiative may require purchasing contracts from BARDA and other government authorities to maintain adequate capacity.

#### *Supporting Innovation Toward More Convenient, Accurate Tests*

Another step to reduce the cost and increase the availability of rapid and reliable COVID-19 diagnostic testing is the development of valid tests that can be administered at home or in other low-risk, convenient settings, such as "self-swab" test materials or other kinds of innovative rapid tests. Swabs administered at home would be a valuable complement to the shift toward telemedicine that is an essential part of the COVID-19 response, and would also reduce the need for and costs of pop-up and drive-through testing capacity, and the extensive associated use of personal protective equipment. Organizations such as the Gates Foundation and Verily, along with some commercial labs and others, are making important progress in [validating the use of self-swab technologies](#) and FDA has [recently clarified](#) that self-swabbing with certain swab types is permitted when done at a testing site under direct health professional supervision.

**To further expand the convenient use of swabs, including self-swabs, private foundations, clinical labs, and private-sector experts can collaborate to expedite clinical validation tests across multiple platforms.** Rather than go manufacturer by manufacturer and platform by

platform, the government entities that are supporting testing could run studies on swab types at the same time they are conducting clinical diagnostic testing.

**The next step in increasing access to more convenient tests would be to validate at-home swabbing or other valid convenient sample collection, and to address the logistical challenges associated with safe and valid home collection of viral samples, and getting the sample to a clinical laboratory in time and under the right conditions so that an accurate and timely result can be generated.** Initial at-home swabbing would likely be done in conjunction with a telehealth appointment and ongoing physician support. This could be a critical tool to help us get past the need for establishing and maintaining large scale testing centers and gaining broader participation in testing.

#### *Planning and Purchasing Commitments for Adequate Testing Capacity Now and for the Future*

These steps to enable valid COVID-19 testing to be conducted on existing or potentially new POC testing platforms, to mobilize a growing supply of PCR testing platforms, and for more convenient locations and processes for testing, through purchasing commitments, will enable the nation's testing gap to be closed faster and with more confidence, with a broader array of more advanced tests. **To sustain this capacity in the months ahead, the task force should continue its capacity monitoring activities and its support for adequate purchase precommitments to reflect expected needs for these tests and associated test materials, as part of an ongoing national surveillance system for the full duration of the COVID-19 threat.** Such precommitments may be especially needed in areas with limited supply, for example more rural areas, to encourage health care providers to sustain ongoing testing capacity with COVID-19 diagnostic test providers.

#### *Communication and Collaboration to Enable Effective Planning*

Health plans, state and local public health authorities, and health systems will be involved in the diagnostic innovation task force's efforts to advance new COVID-19 diagnostic capabilities. **The task force will provide regular updates on the features and expected availability of the new testing capabilities as they are moving through the development process, along with their assessments of capacity gaps.** This will enable payers, health systems, and government authorities to undertake the necessary logistical and clinical care planning to integrate these tests efficiently into a rapidly improving national testing capacity. CDC is [already coordinating](#) a range of such activities now.

Over time, the best approach to testing should evolve; the key goal is to support the innovation needed to assure a sufficient supply of increasingly effective, convenient, and efficient tests to enable current and potential future outbreaks to be contained. While the task force activities we have proposed would play an essential role, **the development of an effective surveillance program will be dependent on investments from Congress.** This must be coupled with coverage and payment steps that support widespread appropriate sampling of patients for coronavirus. COVID-19 will remain a threat past the current epidemic. In the absence of a vaccine, our best defense against a future outbreak or epidemic will be early detection and risk awareness. This is wholly dependent on the easy availability and widespread appropriate use of convenient and



reliable diagnostic tests, coupled to a sentinel surveillance program that surveys the population to detect furtive spread.

### *Public Reporting of Progress Toward Key Objectives*

The new task force or the Federal government's existing cross-agency initiatives to manage diagnostic testing should provide estimates of actual and needed capacity, nationally and regionally, as we have described above.

**At a minimum, publicly-reported metrics on the manufacture, availability, and use of diagnostic tests should include the following:**

- PCR and POC daily test volume and test capacity, including information on the quality of the tests (e.g., sensitivity and specificity)
- Reporting on test utilization, indications, and results, to support a national COVID-19 surveillance system
- Measures of "stress tests" for sufficient rapid testing capacity to detect and respond to new outbreaks in the months ahead
- Contracts in place (including advance purchase) to assure adequate capacity throughout the country will be available through 2020-2021

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## Supplemental Summary of FDA Guidance “Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency”

The U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) released updated [guidance for clinical laboratories and commercial manufacturers of coronavirus \(COVID-19\) diagnostic tests](#) on March 16, 2020. The guidance went into immediate effect and is meant to help accelerate the availability of novel coronavirus (COVID-19) diagnostic tests.

On February 4, 2020, the Secretary of Health and Human Services (HHS) determined that circumstances [justified emergency use authorizations \(EUAs\) of in vitro diagnostics](#) for detection and/or diagnosis of COVID-19 through presumptive qualitative detection of nucleic acid from the COVID-19 in upper and lower respiratory specimens. FDA can, in certain emergency circumstances and when certain criteria are met, therefore authorize the use of unapproved medical products, or unapproved uses of approved medical products.

As such, this document describes several situations in which distribution and testing can begin after a novel test has been validated by the lab or manufacturer, but before FDA has granted an EUA. It also discusses FDA’s role when states are granted a waiver to take over responsibility for testing within their borders, as well as permitted use of serological testing without an EUA.

### *CLIA Laboratory Test Development*

Laboratories certified under Clinical Laboratory Improvement Amendments (CLIA) that meet the CLIA regulatory requirements to perform high-complexity testing may seek to develop their own diagnostic tests for COVID-19. FDA states that they expect that in these situations, labs may need to design and manufacture test kit components such as primers or probes, and potentially may need to use components labeled as “research use only”. FDA will permit labs to use these test kits for diagnostic purposes after the novel test has been validated,<sup>1</sup> while the laboratory is preparing and submitting a EUA request, within a reasonable period.<sup>2</sup> Test reports should contain a general statement that the test has been validated but “FDA’s independent review of this validation is pending.”

FDA also asks that labs provide information on testing capacity to help the Agency monitor the testing landscape and laboratories should also notify all appropriate public health authorities of positive results.

### *Commercial Manufacturers*

Similarly, commercial manufacturers seeking to develop diagnostic test kits for COVID-19 for distribution to clinical laboratories or to health care workers for point-of-care testing<sup>3</sup> may begin

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<sup>1</sup> See pages 9-11 in the guidance for minimum testing requirements

<sup>2</sup> FDA has provided [a template](#) for laboratory submissions and states that it believes “15 business days is a reasonable period of time to prepare an EUA submission for a test that has already been validated.”

<sup>3</sup> This policy does not apply to at-home testing.

distribution for a reasonable time after validation of the test, while the manufacturer is preparing an EUA request.<sup>4</sup> The manufacturer must provide instructions for use of the test and post data about the test's performance characteristics on the manufacturer's website.

To help the agency have a complete picture of the nation's testing capability, FDA asks manufacturers to provide information on testing capacity, as well as the number of laboratories in the U.S. with the required platforms installed.

### *State Authorization of Testing*

The guidance explains that states or territories may choose to authorize laboratories within its borders to develop and perform testing for COVID-19, under the authority of the state's own law and under a process that the state develops. FDA will not object to the use of such tests, and will not review the process adopted by the state or territory.

In these cases, test validation will not be submitted to FDA, and the laboratory will not submit a EUA request to FDA. However, FDA encourages laboratories that develop and perform a test for COVID-19 under this policy to notify FDA and provide information on testing capacity.

### *Serological Testing*

Some laboratories may be developing serology tests that identify antibodies to COVID-19 from clinical specimens, to be used in laboratories or by health care workers at point-of-care (this does not apply to at home testing). Because FDA considers these tests less complex, development and distribution may start after the test has been validated and notification is provided to FDA. Test reports must state that the test has not been reviewed by FDA, that negative results do not rule out infection and should not be used as the sole basis to diagnose or exclude COVID-19 and positive results may result from past or present infection with related coronavirus strains. An EUA would be required if developers want to use serological testing as the sole basis to diagnose or inform infection status.

### *Author Contributions*

We thank Christina Silcox and Monika Schneider for contributing this summary.

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<sup>4</sup> FDA has provided [a template](#) for commercial manufacturer submissions and states that it believes "15 business days is a reasonable period of time to prepare an EUA submission for a test that has already been validated."