

THE DEMOCRATIC COVID-19 RESPONSE
A ROADMAP TO REOPENING BY ENSURING A SPEEDY AND
UBIQUITOUS LAB TESTING SYSTEM (RESULTS)

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The Trump Administration has repeatedly failed to recognize the need for extensive testing to fight COVID-19. The current national surge in COVID-19 cases could and should have been prevented. With accurate, expansive, early testing, the U.S. could have better contained early case clusters and significantly mitigated the widespread community transmission that has overwhelmed the health care system and resulted in tens of thousands of deaths.¹

These missteps surrounding testing have resulted in the need for aggressive social distancing that have upended the economy and American life. For many essential workers, limited testing means every day they go to work and risk exposing themselves and their loved ones at home to COVID-19. Across the country, state and local leaders have attempted to manage a contagious and deadly disease with grossly insufficient data and a lack of federal leadership.² The United States seriously lags behind other countries in its ability to test on a per capita basis.³ And many experts believe the real number of COVID-19 infections and deaths in the United States are significantly higher than reported due to the lack of testing.⁴

To allow people to return to work and reopen the economy before there is an effective vaccine, our public health, government, and business leaders need information about who has COVID-19, who needs to be isolated or quarantined, and who may be immune due to previous infection. The only way to get that information is testing: ubiquitous, fast, free testing, which must be followed by precise contact tracing efforts and the integration of data from national surveillance systems. Experts expect we will need to be able to administer at least 500,000 tests per day.⁵ Testing, while not the only element of an effective response, is a minimum condition for any eventual reduction in social distancing efforts. We cannot safely reopen America without it.

The United States must rapidly increase and optimize COVID-19 testing to collect and analyze the information we need to manage this crisis. The health of our nation—physically, behaviorally, and economically—depends on it.

The path forward requires centralized leadership that only the Executive Branch can provide. Given the repeated failures of the Trump Administration to effectively and rapidly respond to the COVID-19 crisis—including a continued failure to address testing shortages and insufficient data on the spread of the disease—Senate Democrats are putting forward detailed proposals outlining how the Administration should ramp up testing and public health capacity across the country.

¹ <https://www.nytimes.com/2020/04/11/us/politics/coronavirus-trump-response.html>

² <https://hbr.org/2020/03/why-is-the-u-s-behind-on-coronavirus-testing>

³ <https://ourworldindata.org/covid-testing>

⁴ <https://www.nytimes.com/2020/04/05/us/coronavirus-deaths-undercount.html>

⁵ <https://www.forbes.com/sites/steveforbes/2020/04/08/to-get-our-economy-moving-focus-on-testing-for-coronavirus/#11429e7373f2>

Democrats' proposals include the following major components:

1. Requiring a strategic plan to leverage a “whole of society” response;
2. Emergency funding to enable rapid scaling of testing and the full range of activities that support testing and maximize its impact;
3. Pipeline to develop, validate, and allocate accurate, reliable tests to ensure adequate supply;
4. Structures to administer tests in every community across the country;
5. Robust public health infrastructure to respond to results and better contain COVID-19; and
6. Transparency and accountability across the testing system.

A Roadmap to Reopening by Ensuring a Speedy and Ubiquitous Lab Testing System (RESULTS)

Requiring a Detailed Strategic Plan

Our nation has faced few challenges as daunting as the COVID-19 pandemic. Industry, academia, and state and local leadership are essential to successfully standing up effective testing—but they require the convening power of the federal government to bring together all the moving pieces.

The Administration has allowed testing efforts to fall far behind, and has failed to offer a clear plan to address this shortcoming.⁶ Democrats demand a clear, detailed plan to rapidly scale and optimize COVID-19 testing in the United States. This plan must take a “whole of society” approach that, led by the federal government, will quickly scale and optimize COVID-19 testing, mitigate additional community spread, and help get America back to work.

A comprehensive plan will include extensive detail, including timelines for completion, on how the Trump Administration plans to:

1. **Create a pipeline for the development and manufacturing of tests and testing supplies**, including specific plans to:
 - a. Establish a highly functioning supply chain with sufficient availability of all necessary testing materials and supplies;
 - b. Explicitly assess the rate-limiting factors and bottlenecks in the supply chain and communicate this information publicly to state, local, tribal, and territorial leaders, academic and industry stakeholders, and health care providers; and
 - c. Develop and validate accurate, reliable tests for COVID-19, with a focus on tests and processes that deliver rapid results.

2. **Work to efficiently and comprehensively administer tests** across the United States, including specific plans to:
 - a. Allocate tests and other necessary supplies in a manner that optimizes public health and equity, with a focus on:
 - i. Initially prioritizing access for health care workers, first responders, and other essential personnel; and
 - ii. Administering mass testing without increasing rates of transmission;
 - b. Ensure sufficient testing-related personnel;
 - c. Ensure sufficient laboratory capacity and prioritize rapid turnaround times for test results;
 - d. Enforce the *Families First Coronavirus Response Act* to ensure patients are tested with no cost sharing; and
 - e. Implement an antibody testing program in the United States to identify people who are potentially immune to COVID-19.

⁶ <https://www.vox.com/2020/4/10/21214218/trump-coronavirus-testing-social-distancing>

3. **Prioritize the health and safety of the entire population** in using testing to inform policy decisions, including specific plans to:
 - a. Ensure equity in the response to COVID-19, including addressing inequities in outcomes based on race, ethnicity, sex, age, disability status, geographic location, and more;
 - b. Achieve sufficient testing capacity in every community, including those that often struggle to access health care: rural and frontier areas, communities with health professional shortages, medically underserved areas, underserved populations, and Native Americans, including Indian tribes, tribal organizations, and urban Indian organizations; and
 - c. Make testing available to vulnerable populations at increased risk of morbidity or mortality related to COVID-19, including people with disabilities.

4. **Use Testing Data to Protect the Public Health.** This will require unprecedented investment in, and implementation of, a robust public health workforce and infrastructure, which will perform contact tracing as well as leverage data produced by mass testing, including specific plans to:
 - a. Strengthen electronic reporting of test results and patient outcomes;
 - b. Expand epidemiological surveillance for COVID-19 to track cases and, if applicable, immunity;
 - c. Conduct extensive high precision contact tracing, isolation, and quarantine, including specific plans to quickly recruit and train a significant new contract tracing workforce; and
 - d. Leverage data about health disparities to ensure an equitable response.

Emergency Funding for Testing Activities

Testing is one of the most critical elements to beating this virus. **Congress should designate \$30 billion in new emergency funding to support the rapid expansion and optimization of testing for COVID-19 in the United States.** While the funds would be directed to a broad range of testing and related activities, including critical surveillance and contact tracing, a significant portion of this funding should be dedicated to:

- Optimize the testing supply chain at a national level, addressing manufacturing shortages of testing kits and supplies through increased production, including through matching excess supplies or personnel with demand in other locations, centralized procurement of testing supplies, guaranteed contracts to manufacturers, and effective use of the Defense Production Act, when necessary; and
- Develop and validate different types of tests necessary, including rapid, molecular point-of-care and at-home testing platforms, to effectively monitor and control COVID-19.

Broadly, the funding should support testing-related activities at federal agencies and state, local, territorial, and tribal health departments and other public health organizations, health care facilities, academia, laboratories and testing sites. Funding should be made available for personnel required to conduct tests, transparent public reporting of test results, construction or enhancement of testing or testing-related facilities, communications about testing, oversight of

laboratories and tests to ensure test validity and reliability, and programs to facilitate at-home testing, especially for high-risk populations.

Improving the Test Development and Supply Pipeline

Given the widespread community transmission of COVID-19 in the United States, we must test millions of Americans to get the information public health experts need to determine when and how to begin reopening communities and reducing social distancing measures.⁷ This will require a significant volume of tests—potentially in the hundreds of millions.⁸ Congress must ensure a functioning supply chain and support the development of various types of tests. To ensure a successful pipeline for COVID-19 tests and testing supplies in the near term, Congress could:

Establish a highly functioning, transparent supply chain. This includes quickly addressing shortages by scaling manufacturing and production, procuring sufficient supply of the materials required to administer, process and analyze tests, and utilizing logistics infrastructure to move materials through the supply chain as efficiently as possible. To effectively optimize the supply chain, the government must leverage the full expertise of academia, industry, state and local governments, health care leaders, and public health organizations.

To achieve this goal, Congress could:

- Address shortages and optimize the supply chain with legislation that:
 - Develops mechanisms that incentivize domestic manufacturing of testing supplies, including providing funding to cover costs of retooling factories to shift to medical supply production and technical assistance to reduce regulatory barriers for firms pivoting their production;
 - Compels sharing of intellectual property needed to expand test manufacturing, if necessary;
 - Compels manufacturing of testing supplies that are in critical shortage, including ensuring effective use of the Defense Production Act, when necessary; and
 - Guarantees purchases of products or materials commissioned under any of these mechanisms or contracts, using excess supply to seed the restock of the Strategic National Stockpile.
- Direct the Department of Health and Human Services (HHS) and the Federal Emergency Management Agency (FEMA) to compile and publicly share information about testing supply inventory and shortages on a weekly basis, including:
 - Supply of diagnostic tests available nationally;
 - Daily capacity of laboratories to process tests, including information on wait times for results and inventory of tests processed by laboratory, type of test, and state;
 - Distribution of tests by location;
 - Supply of materials required to process and analyze tests, including reagents; and

⁷ https://ethics.harvard.edu/files/center-for-ethics/files/white_paper_6_testing_millions_final.pdf

⁸ *Id.*

- Clear explanation of exactly how the federal government is intervening in the commercial supply chain, including how supplies are being allocated.

Congress must also push the Administration to ensure development of a variety of testing methods, including RNA tests, antigen tests, and serological tests, with a focus on point of care tests that deliver rapid results. Congress could:

- Direct FDA to consult with CDC and NIH on the development of policies on the review and oversight of tests that reflect the latest research on COVID-19 immunity; and
- Require FDA to communicate to the public which available tests, including RNA tests, antigen tests, and serological tests, deliver reliable results.

Rapidly Scaling and Optimizing Testing Administration

To mitigate and control the spread of COVID-19, we need to ensure that testing is ubiquitous, accurate, reliable, fast, and free. A massive supply of tests has limited value if they are not combined with necessary medical supplies, health care personnel, and lab capacity to quickly test patients. To ensure success across the spectrum of testing administration activities, Congress must ensure that we achieve the following goals:

Deploy tests and other medical supplies to communities that need them. To test effectively, we must optimize supply as much as possible to limit the number of communities facing shortages. Congress could:

- Direct the Administration to establish partnerships with commercial and community entities to stand up additional testing sites nationwide, including major pharmacy chains, national retailers, and others, with a focus on accessibility of testing to people with disabilities, older Americans, and individuals with underlying medical conditions or weakened immune systems; and
- Extend and/or expand the FEMA/HHS initiative that established community-based testing sites.

Leverage data about health disparities to adjust the response and ensure that no community is left to fight COVID-19 without the resources and support they need. Congress could:

- Require and enable public reporting on demographic information for COVID-19 cases, including sex, race, ethnicity, disability status, and whether a patient is a health care provider;
- Require independent review of data to better understand health disparities in the response to COVID-19 and propose policy recommendations to address them; and
- Require HHS to adjust resource allocation in response to findings about where gaps in testing fall along demographic lines.

Establish sufficient public health and medical personnel to administer tests to patients in their communities. To do this, Congress could:

- Increase funding for the National Health Service Corps and the Nurse Corps in order to expand the number of health care providers that receive scholarships and loan repayment options in exchange for practicing in underserved areas; and

- Expand the public health workforce by enacting a loan repayment program for public health professionals who agree to serve two years in a local, state, or tribal health department.

Guarantee tests are available to patients with no cost sharing. The *Families First Coronavirus Response Act* required all coverage to provide testing without any out-of-pocket costs and prevented commercial insurers from limiting access using protocols like prior authorization. Congress must take steps to ensure these steps are being implemented appropriately and keep down the cost of testing. Congress could:

- Establish an ombudsman operated jointly by the Departments of Health and Human Services and Labor to serve as a single point-of-contact for patients who have been unfairly charged for testing and associated services; and
- Strengthen the price gouging policy from the *CARES Act* to ensure that insurers are paying providers a fair reimbursement without being over-charged for these critical tests.

Enhancing Public Health Infrastructure

A strong public health system is needed both to expand testing and to turn data into information that facilitates a quick response by working to contain COVID-19 clusters as they appear. This will require a massively scaled up public health workforce and strengthened foundational capabilities in public health departments across the country. Once we build these capabilities, we must sustain them for the long-term. To accomplish these goals, Congress could:

Invest in foundational public health capabilities. Optimizing the public health impact of testing requires investment in strengthening public health infrastructure across the country. Congress should establish a core public health infrastructure fund that reaches \$4.5 billion annually to strengthen the local public health system in the United States, bolstering the Nation's ability to strengthen testing, contact tracing, and targeted isolation related to the COVID-19 pandemic.

This fund would support critical activities and functions including assessment (e.g. surveillance, epidemiology, and laboratory capacity), all-hazards preparedness and response, policy development and support, communications, community partnership development, organizational competencies, and accountability and performance management. Establishing and maintaining each of these elements for the long-term will be critical to ensuring and sustaining a successful testing system going forward.

Support public health data modernization. The *CARES Act* invested \$500 million in public health data modernization. It is long past time to strengthen and modernize public health data systems at CDC and public health departments and laboratories across the country, including to automate test result reporting, improve connectivity, and bolster surveillance to maximize the public health benefit of testing. Congress should continue to bolster this critical work.

Furthermore, it is essential that a portion of the emergency funding proposed above be allocated to immediately strengthen and scale up existing public health programs to address immediate

needs related to surveillance, testing and contact tracing to enable us to better contain COVID-19 and begin reducing social distancing measures. Emergency funds could be expended to:

Strengthen electronic results reporting of test results and patient outcomes to keep decision makers informed of the latest case data. The lack of transparency around the COVID-19 response, particularly around testing, has left states, health care providers, and the public in the dark. Congress could:

- Establish national results reporting; and
- Demand same-day results reporting on all COVID-19 tests, including data about various types of tests conducted, information necessary for contact tracing and public health follow up, and health outcomes for patients with COVID-19 diagnoses.

Expand disease surveillance systems to better track active COVID-19 cases and rates of exposure at the community level, while protecting patient privacy. Congress could bolster these systems to:

- Collect data on inpatient and outpatient cases of COVID-19 and summaries of geographic spread;
- Determine rates of infection;
- Determine rates of potential immunity; and
- Establish a secure national clearinghouse for all COVID-19 testing data that protects privacy and is accessible by federal, state, local, territorial, and tribal public health officials;

Ensure we can conduct extensive, high precision contact tracing, isolation, and quarantine. Funds could be made available to significantly expand the public health workforce to increase capacity for follow-up on potential COVID-19 exposures, with a heavy focus on contact tracing, quarantine, and isolation.

Ensuring Transparency and Accountability

All aspects of a public health response – particularly during an international crisis – must be driven by public health and science. Accordingly, efforts to scale up the testing system must ensure resources are allocated according to public health needs, not used as a form of political patronage. In enacting a suite of policies to rapidly scale up and optimize COVID-19 testing in the United States, Congress could include protections to ensure that taxpayer dollars are doing the most they possibly can to protect the health and wellbeing of every American.

To ensure transparency and accountability in the implementation of these testing proposals, Congress could:

Eliminate opportunities for political interference in the testing system, including prohibiting the President, his immediate family, Cabinet members, and Members of Congress from benefitting financially from any component of the COVID-19 testing system.

Place strong transparency reporting requirements on supply chain optimization, including weekly reporting on:

- requests for tests and testing supplies from state, local, territorial, and tribal governments;
- clear documentation of unfulfilled requests; and
- public health justification for allocation decisions.

Require independent analysis on the effectiveness of COVID-19 testing, with specific attention to the effort to expand and optimize testing in an effort to safely begin reducing social distancing efforts.