

LAMAR ALEXANDER, TENNESSEE, CHAIRMAN

MICHAEL B. ENZI, WYOMING
RICHARD BURR, NORTH CAROLINA
RAND PAUL, KENTUCKY
SUSAN M. COLLINS, MAINE
BILL CASSIDY, M.D., LOUISIANA
PAT ROBERTS, KANSAS
LISA MURKOWSKI, ALASKA
TIM SCOTT, SOUTH CAROLINA
MITT ROMNEY, UTAH
MIKE BRAUN, INDIANA
KELLY LOEFFLER, GEORGIA

PATTY MURRAY, WASHINGTON
BERNARD SANDERS (I), VERMONT
ROBERT P. CASEY, JR., PENNSYLVANIA
TAMMY BALDWIN, WISCONSIN
CHRISTOPHER S. MURPHY, CONNECTICUT
ELIZABETH WARREN, MASSACHUSETTS
TIM Kaine, VIRGINIA
MARGARET WOOD HASSAN, NEW HAMPSHIRE
TINA SMITH, MINNESOTA
DOUG JONES, ALABAMA
JACKY ROSEN, NEVADA

United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

DAVID P. CLEARY, STAFF DIRECTOR
EVAN SCHATZ, DEMOCRATIC STAFF DIRECTOR

<http://help.senate.gov>

March 5, 2020

The Honorable Mike Pence
Vice President of the United States
The White House
Office of the Vice President
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Vice President Pence:

As I hear from Washington state residents and people across the country, I want to be able to provide them answers about the availability of diagnostic tests for the 2019 Novel Coronavirus (COVID-19). I am extremely frustrated by how the Trump Administration has handled the deployment of such tests, including how it has communicated to Congress and the public about when, where, and to whom tests will be available. In the midst of this public health emergency, the Trump Administration must do better.

The Administration has failed several times to take steps that could expedite the COVID-19 response, resulting in a slower deployment of tests to people in need. In February, the Centers for Disease Control and Prevention (CDC) distributed a three-component diagnostic test to state and local health labs.¹ Unfortunately, when some of those laboratories attempted to validate the tests, they delivered inconclusive results, and only six state laboratories verified the test for use.² The CDC cited manufacturing defects and promised a replacement for the three-component test.³ The Administration was unclear, however, about exactly how long that would take and, as of last week, CDC was still managing the bulk of testing, requiring states across the country to ship specimens to agency headquarters in Atlanta for testing.⁴ CDC has now deployed a two-component replacement, and state lab testing is finally beginning to scale up.⁵ As a result of

¹<https://www.cdc.gov/coronavirus/2019-ncov/summary.html>;

<https://www.nytimes.com/2020/03/02/health/coronavirus-testing-cdc.html>

² <https://www.politico.com/news/2020/02/20/cdc-coronavirus-116529>

³ <https://www.nytimes.com/2020/03/02/health/coronavirus-testing-cdc.html>

⁴ <https://www.nytimes.com/reuters/2020/02/24/world/asia/24reuters-china-health-usa-testing.html>

⁵ <https://www.cdc.gov/coronavirus/2019-ncov/summary.html>;

<https://www.oregonlive.com/health/2020/02/coronavirus-testing-should-be-ready-in-every-state-by-end-of-next-week-cdc-says.html>; <https://www.politico.com/news/2020/03/01/health-officials-probe-coronavirus-cdc-118523>; Senate HELP Committee Hearing, "An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus," March 3, 2020.

these delays; fewer than 500 patients in the United States were tested through January and February, during a time when experts now believe the virus was circulating in Washington state.⁶

As the number of cases rise across the country and we learn more about how this virus spreads, the federal government must be making all reasonable efforts to deploy tests where they are needed. Yet, I remain concerned by conflicting estimates of how many tests will actually be deployed and when. This type of confusion only adds to the uncertainty and anxiety many are feeling in my home state. Last weekend, you said approximately 15,000 test kits were being shipped to labs, with each kit able to test between 700 to 800 patient specimens.⁷ Yet on Sunday, CDC said it had shipped only 47 test kits to public health labs.

At a HELP Committee hearing earlier this week, Food and Drug Administration (FDA) Commissioner Stephen Hahn told me his agency is hearing from commercial test manufacturers about their ability to deploy 2,500 test kits, including to academic and commercial labs, by the end of this week. According to Commissioner Hahn, this should allow labs to perform up to one million tests, once they are validated.⁸ Vice President Pence announced yesterday that 1.5 million tests will be available this week.⁹ FDA has also indicated that, by the end of next week, the production capacity of commercial tests by just one commercial test manufacturer could reach up to four million tests per week.¹⁰

Yet, in projecting commercial lab capacity, the Association of Public Health Laboratories (APHL) said its member laboratories are “a couple of weeks away from being able to deploy a million tests through this process.”¹¹ In speaking about its public health lab capacity, APHL estimated it will be able to conduct about 10,000 tests per day when all of its 100 member labs are running. It is difficult to tell my state and people across the country what to expect with such conflicting estimates.

I also hope to gain clarity for health experts and officials in my state about current CDC testing criteria. Yesterday, CDC posted revised criteria on its website, now directing clinicians to use their judgment for whether a patient should be tested.¹² Earlier this week, you announced “fast-tracking” for people who may have the virus, but it is not yet clear what that process looks like.¹³

We need to understand what is going wrong around testing, and the lack of transparency from the Administration so far is unacceptable. The President is contradicting his public health experts in communicating about the scope of this disease and what his Administration is doing to respond. The leadership at Department of Health and Human Services (HHS) is facing mounting

⁶ <https://www.politico.com/news/2020/03/02/azar-crosshairs-delays-coronavirus-tests-118796>

⁷ <https://www.nytimes.com/2020/03/03/health/coronavirus-tests-fda.html?>

⁸ Senate HELP Committee Hearing, “An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus,” March 3, 2020.

⁹ <https://www.kivitv.com/news/coronavirus/us-ready-to-distribute-1-5-million-coronavirus-tests-to-states>

¹⁰ <https://www.reuters.com/article/brief-fda-says-in-addition-to-tests-cdc/brief-fda-says-in-addition-to-tests-cdc-is-distributing-to-public-health-labs-additional-cdc-tests-are-being-produced-by-commercial-test-manufacturer-idt-idUSFWN2AX0D8>

¹¹ <https://www.nytimes.com/2020/03/03/health/coronavirus-tests-fda.html?>

¹² <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html>

¹³ <https://www.nytimes.com/2020/03/03/us/politics/trump-us-coronavirus.html>

criticism for its management of the response broadly, including specifically on issues surrounding testing.¹⁴ HHS is launching an investigation into the first round of manufacturing issues with CDC's diagnostic tests, but has not announced who will be conducting that inquiry and whether it will be conducted by staff who have been part of the COVID-19 response.¹⁵ At least three individuals have been designated as "leaders" or "coordinators" of the federal government's COVID-19 response.¹⁶

My constituents in Washington state – from public health officials to health care providers to those who fear they are sick – are looking for answers. Please respond to the following questions by no later than March 19, 2020:

1. Please provide a detailed timeline of CDC's development and deployment of the COVID-19 diagnostic tests.
2. Please provide an explanation for why the COVID-19 diagnostic test approved by the World Health Organization was not used.
3. Please provide estimates for the following data on a weekly basis, for at least the next six weeks. Please provide the data for tests manufactured by CDC, as well as current expectations regarding tests manufactured by commercial laboratories:
 - a. How many test kits will be deployed?
 - b. How many tests will be deployed?
 - c. How many patients are able to receive testing?
 - d. What is the turnaround time for patients to receive test results?
4. Please provide estimates for the following data on a weekly basis, for at least the next six weeks. Please provide information on current expectations regarding tests manufactured by commercial and academic labs:
 - a. How many test kits will be ready for use?
 - b. How many tests will be ready for use?
 - c. How many tests are needed for diagnosis of an individual patient?
 - d. What is the turnaround time for patients to receive test results?
5. How does CDC determine the criteria for evaluation of persons under investigation (PUI)?
 - a. Now that CDC has expanded the criteria for testing, is the agency providing additional guidance for clinicians on how to decide whether to test patients?
 - b. How are CDC, FDA, and other federal health agencies working with health care providers, medical facilities, commercial and academic labs, and state public health labs to determine how to accommodate a likely substantial influx of patients requesting to be tested?
6. What is the scope of the HHS investigation into the first round of diagnostic tests?
 - a. Please provide the names and titles of the individuals conducting the investigation.
 - b. When will the investigation be complete?
 - c. Will the results of the investigation be shared with the public?

¹⁴ <https://www.politico.com/news/2020/03/02/azar-crosshairs-delays-coronavirus-tests-118796>

¹⁵ <https://www.politico.com/news/2020/03/01/health-officials-probe-coronavirus-cdc-118523>

¹⁶ <https://www.politico.com/news/2020/02/27/white-house-coronavirus-response-debbie-birx-117893>

Thank you in advance for your attention to this matter. If you have any questions, or would like to further discuss compliance with this request, please contact Elizabeth Letter with Senator Murray's HELP Committee Staff at 202-224-0767.

Sincerely,



PATTY MURRAY

United States Senator

Ranking Member, Senate Health, Education, Labor, and Pensions Committee

cc: The Honorable Alex Azar
Secretary of Health and Human Services

Dr. Robert Redfield
Director of the Centers for Disease Control and Prevention

The Honorable Stephen Hahn
Commissioner of Food and Drugs