

Select Subcommittee on the Coronavirus Crisis

Hearing on:

“The Administration’s Efforts to Procure, Stockpile, and Distribute Critical Supplies”

July 2, 2020

Questions for The Honorable Brett Giroir, M.D.

Assistant Secretary for Health

Department of Health and Human Services

Congressman Raskin

1. Please describe all plans to provide continuing federal support for community testing sites.

The Community Based Testing Sites initiative has been a profound success and efforts to support these endeavors moving forward will continue. The federal government has broadened the community testing infrastructure by continued support of retail and pharmacy partnerships in more than 1,849 locations in all 50 states, the District of Columbia and Puerto Rico, which collectively have conducted nearly 4 million tests as of November 18.

This pharmacy and retail partnership provides convenient access to COVID-19 testing, but it is also a bridge for retailers to implement new regulatory flexibilities and expanded reimbursement options HHS has provided through private insurance, Medicare, Medicaid, and the newly expanded authority given to pharmacists to order and administer COVID-19 testing; this effort is also known as CBTS 3.0. Over 2,000 retail pharmacy stores (CVS, Walmart, Walgreens) are providing COVID-19 testing using new regulatory and reimbursement options.

Surge testing, also known as CBTS 4.0, has been established in 17 states and 4500 locations to date. As of November 18, more than 480,276 tests have been conducted at these sites. The turnaround times for our current federal surge testing sites now open is less than 2 days. As of November 18, there are currently 182 active surge testing sites. Further information can be found at this link:

<https://www.hhs.gov/coronavirus/community-based-testing-sites/index.html>.

2. What effort is HHS undertaking to track current and projected needs for testing kits and related supplies across the country? Please describe how often these projections are updated, what inputs and assumption are used to determine them, which populations the projection account for, and any breakdown of projected need by state or other locality.

HHS is constantly tracking the current and projected needs of the testing infrastructure of the United States to meet and exceed the testing needs of our country. HHS is in constant communication with industry, state and local leaders, and other Federal Government partners to track current and projected testing needs and to make the necessary improvements as needed. The projects are constantly updated to account for new technologies and novel tests that receive emergency use authorizations as well as supply chain constraints. Through our efforts to galvanize the testing infrastructure of the United States, the national capacity for testing will exceed 126 million tests in November. As of November 18, the U.S. has accomplished over 169.7 million tests, at an average current rate of over 1 million tests per day.

3. Does the country currently have enough testing kits and related supplies to deal with the potential for an exponential increase in coronavirus cases, and all of the hospitalizations that will go with that?

As of November 18, the U.S. has accomplished over 169.7 million tests, at an average current rate of over 1 million tests per day. In terms of overall testing capacity, not counting pooled samples, and only assuming technologies with current EUAs, national capacity for testing will exceed 126 million in November and continue to increase through 2020. Based on current information, we project the United States will have the capacity to conduct over 147 million tests in the month of December.

4. How long do you intend to remain in your role as the country's lead testing official and is there a date on which you intend to return to your regular duties at HHS? Which federal official will be responsible for coordinating the national testing strategy after you?

As an official who was appointed by President Trump, as long as I am at HHS, I will maintain my role as the Country's lead testing official and ensure this important work continues.

Congressman Kim

1. Please describe all efforts to purchase testing kits and related supplies in bulk and to negotiate better prices and faster delivery than would be available to multiple purchasers making smaller orders? Is there a plan to continue to procure testing kits and related supplies through the Strategic National Stockpile to meet the increase in demand?

HHS constantly examines where we can make the best investments and procurements to meet the testing needs of the nation. The Office of the Assistant Secretary for Health (OASH) is leading efforts to increase the availability of COVID-19 tests. On April 6, 2020, HHS announced that it would begin purchasing Abbott ID Now devices to increase point of care testing capacity. ¹As of November 23, 2020, the Strategic National Stockpile (SNS), has distributed 560 Abbott ID Now testing devices, 477 control kits,

¹ <https://www.hhs.gov/about/news/2020/04/06/hhs-supports-state-territorial-and-tribal-public-health-labs-with-covid-19-rapid-point-of-care-test.html>

and 6,157 test kits (each kit contains materials to perform 24 tests) to jurisdictions across the country. In addition, OASH is procuring and distributing Abbott BinaxNOW tests. On August 27, 2020, the Administration announced that a \$760 million contract was awarded to Abbott for the delivery of 150 million rapid BinaxNOW COVID-19 Ag Card point-of-care tests. The Abbott BinaxNOW COVID-19 Ag Card, which recently received an EUA from the FDA, does not require instrumentation and will deliver COVID-19 test results in 15 minutes. HHS will distribute approximately 100 million tests to states and territories through the end of December 2020, distributed by proportion of their population. Governors will determine the best use of tests for their states; suggested deployment includes use cases for which a low-cost, rapid, easily administered test is uniquely able to fill state needs, such as opening of K-through-12 schools through testing of teachers, staff, and students; protecting first responders: supporting critical infrastructure: enhancing higher education programs; and other priorities the governors deem fit. Overall, we have distributed over 58 million BinaxNOW tests as of November 18.

Further information about point of care test distribution can be found:
<https://www.hhs.gov/coronavirus/testing/rapid-test-distribution/index.html>

On October 13, HHS in collaboration with the Department of Defense (DOD) awarded a \$481 million Other Transaction Agreement to Cue Health, Inc. to expand U.S. production capacity for a cartridge-based point-of-care COVID-19 molecular test that produces results in about 20 minutes. It is FDA-authorized for use in anyone suspected of having COVID-19 by their healthcare provider, whether asymptomatic or symptomatic. This investment will allow Cue to expand its industrial base and increase domestic production to 100,000 COVID-19 test kits per day, enabling this technology to be deployed throughout our testing ecosystem to benefit all Americans. Cue fills an important niche in the testing ecosystem between rapid point-of-care antigen tests and sophisticated laboratory-based PCR tests.

Starting in May and through November 2020, September 11, the Federal Government has distributed over 167 million swabs and more than 174 million tubes of transport media. These supplies are provided to states throughout the month to equip them with sufficient materials to meet their specific testing goals.

The Strategic National Stockpile is also being updated to be prepared for testing needs into the future as well.

2. Where is the U.S. currently obtaining testing kits and related supplies? Please provide source information by company and place of origin including items imported and domestically produced.

The testing infrastructure of the United States is supported and resourced both domestically and internationally. The federal government has galvanized the entire industry to support the United States testing needs. The Federal Government has used the

Defense Production Act to further expand domestic testing supplies and capability to unprecedented levels.

One example of leveraging the DPA to increase the production of supplies was the investment in Puritan Medical Products. After in-depth market research on testing availability and producibility, the Federal Government applied DPA title III authorities to award a \$75.5 million contract to Puritan Medical Products to increase foam specimen collection swab manufacturing capacity by 20 million swabs per month. An additional swab requirement was identified for both COVID-19 and flu specimen collection; a second expansion investment of \$51.15 million CARES Act funds in Puritan (the only U.S. based manufacturer of flock tip swabs) to produce an additional 45 million flock tip swabs per month by March 2021. HHS is leveraging all authorities, including DPA title III, to acquire additional testing capability.

3. Regarding testing kits and related supplies, how much is the domestic private sector able to produce beyond its current output, and what are the barriers currently preventing this production?

The Federal Government is coordinating across the entire testing supply chain to ensure that all production is at its highest levels to provide all of the materials possible to support the testing infrastructure of the United States.

4. Before issuing contracts with private testing companies, did the federal government take steps to ensure that the contracted companies had the capabilities to meet expectations set out in the contracts?

Yes, the Federal Government conducts a rigorous examination of the abilities of the companies we enter into contracts with. We have been proactive in ensuring that the needs of the testing industry are met and addressed during this crucial time. Various Defense Production Act actions and investments have been made to ensure the testing infrastructure is robust and able to meet the needs of the American People.