COVID-19 Second Wave Preparedness

Part 1: Testing & Surveillance

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Containing a Second COVID-19 Outbreak – Testing and Surveillance

I. Testing

A. What are the modalities of testing, and what supplies are needed for each type of test?

- There are three main types of testing involved with COVID-19: viral nucleic acid, antigen, and serological. Viral nucleic acid testing and antigen testing are used to diagnose COVID-19. Viral nucleic acid testing detects the virus through its genetic material. Antigen testing detects the virus by proteins on or in the virus. Serological testing is used to detect antibodies in people who have already been infected and have survived COVID-19. Detailing the types of testing helps to understand what specific supplies and equipment are needed for each kind of test.

    - **Viral nucleic acid amplification tests or molecular tests (PCR or RNA testing)**: These tests indicate if a patient is actively infected with COVID-19. The tests detect the presence of characteristic sequences of COVID-19 genetic material, ribonucleic acid (RNA), in respiratory samples of patients. If the viral RNA is detected, it suggests COVID-19 is likely present.[1] Nucleic acid amplification testing requires respiratory samples from the patient since COVID-19 is a respiratory virus.[2] Nasopharyngeal swabs are commonly used to collect the sample for this type of testing, though the U.S. Food and Drug Administration (FDA) has expanded the types of swabs that can be used to collect a sample and also approved a test that utilizes a saliva sample, which does not require a swab. Samples are processed and tested for COVID-19 using a test that includes the extraction of RNA from the patient specimen, conversion to DNA, and PCR amplification with COVID-19 primers. The RNA extraction and DNA conversion process is also known as reverse-transcriptase polymerase chain reaction (RT-PCR). There are two types of these tests: lab-based and rapid point-of-care.

        - **Lab-based tests (lab machines or laboratory developed tests by CLIA-certified labs)**: Specimens (nasal or throat swabs) are usually collected at a doctor's office or a hospital. The specimens are then sent to a lab to extract the RNA, which is then converted to DNA. This material is amplified by PCR with COVID-19 specific primers. The samples are then analyzed for presence of COVID-19 viral RNA, indicating an active infection. Often due to the transport time to get a sample to the laboratory, this process can take days to get the test results. This is an open testing system, meaning that parts of the test or supplies needed to collect the sample can come from different

[1] Amy Maxmen, *Thousands of coronavirus tests are going unused in US labs*, NATURE (Apr. 9, 2020), *available at* https://www.nature.com/articles/d41586-020-01068-3.

[2] American Society for Microbiology, COVID-19 Testing FAQs (Apr. 29, 2020), *available at* https://asm.org/Articles/2020/April/COVID-19-Testing-FAQs.

manufacturers. Testing capacity is dependent on supplies, including swabs, transport media, and RNA extraction kits. One PCR test developed by Rutgers University included by the FDA under an "umbrella" Emergency Use Authorization (EUA) uses saliva specimens, thus negating the use of swabs and transport media.[3] As alternatives to lab-based, swab-specimen PCR testing continue to emerge, pressure on the supply chain for testing can be reduced.

- **Rapid point-of-care tests**: This category involves decentralized molecular tests meant to bring lab-quality test results while the patient is with the provider to guide treatment decisions.[4] These tests, and any accompanying equipment, need to be small or portable, require minimum sample processing, and require little training to use correctly in low-complexity testing environments. The recently authorized tests from Cepheid, Mesa Biotech, and Abbott Laboratories use instruments that have already been approved for other indications, such as influenza testing.[5] These are closed testing systems, meaning the test manufacturer has included all the parts of the test kit. While some medical experts do not believe this type of testing will be the solution to high-volume testing, it is a solution where fast results are needed and can be used as part of an overall testing strategy.

- **Antigen tests**: These tests look for antigens that the virus produces, which show its presence in blood and saliva. Antigen tests are less precise than PCR tests, but enable fast and widespread testing. Moreover, the advantage of antigen testing over PCR tests is that it can show whether the virus is intact and still viable, and thus whether the patient is infectious. In some cases, with PCR testing, there are patients who have recovered and are no longer infectious but are still testing positive because not all of the virus RNA has cleared from the body. Dr. Deborah Birx, the White House Task Force Coordinator, has described antigen testing as a significant testing "breakthrough."[6] FDA recently granted an EUA to Quidel Corporation for the first antigen test for COVID-19.[7]

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[3] Rutgers University, *New Rutgers Saliva Test for Coronavirus Gets FDA Approval* (Apr. 13, 2020), *available at* https://support.rutgers.edu/news-stories/new-rutgers-saliva-test-for-coronavirus-gets-fda-approval/. The Rutgers Clinical Genomics Laboratory also received an EUA to permit testing of saliva samples self-collected by patients at home. U.S. Food and Drug Administration, *Coronavirus Update: FDA Authorizes First Diagnostic Testing Using At-Home Collection of Saliva Specimens* (May 8, 2020) *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-diagnostic-test-using-home-collection-saliva.

[4] Madeleine Johnson, *Experts debate whether point of care COVID-19 testing can help flatten the curve*, MODERN HEALTHCARE (Apr. 8, 2020), *available at* https://www.modernhealthcare.com/clinical/experts-debate-whether-point-care-covid-19-testing-can-help-flatten-curve.

[5] *Id.*

[6] NBC News, *Birx: U.S. needs "breakthrough" on antigen testing to aid in reopening* (Apr. 27, 2020), *available at* https://www.nbcnews.com/politics/meet-the-press/birx-u-s-needs-breakthrough-antigen-testing-aid-re-opening-n1192901.

[7] U.S. Food and Drug Administration, *Coronavirus Update: FDA Authorizes First Antigen Test to Help in the Rapid Detection of the Virus that Causes COVID-19 in Patients* (May 9, 2020), *available at* https://www.fda.gov/news-

- **Serological/serology tests**: Serology tests are blood tests that seek to identify specialized proteins and molecules made to detect human antibodies against the COVID-19 virus and produce a signal that can be read by an instrument or produce a color that can be read visually by a healthcare practitioner. Serology tests are not a diagnostic test, meaning that they should not be used alone to diagnose an active infection, but can identify past infections. Serology tests can be used on an individual level to determine if a person has antibodies against the COVID-19 virus, and on a more widespread basis to determine approximate levels of community exposure to the virus.

B. What are the component parts of diagnostic tests for COVID-19, and is there an adequate supply of each of these parts?

- There are three parts in the diagnostic testing process: (1) sample collection; (2) sample processing; and (3) sample analysis. For each part of the process, there are associated supplies. Component parts include nasal swabs, RNA extraction kits, reagents, and transport media.
  - For sample collection, the component parts involved are nasal swabs, transport media, and collection tubes.
  - For sample processing, the component parts involved are RNA extraction reagents.
  - For sample analysis, the component parts involved are other reagents (e.g., primers, probes, master mix).
  - Almost all of these component parts also apply to antigen testing that use nasal and respiratory samples, with the exception of RNA extraction reagents. Serology testing does not require swabs, transport media or the same reagents as diagnostic testing.
- Nasal swabs are made of plastic and cotton. Pre-pandemic, the cotton swabs were primarily sourced from two suppliers, with only one of those being a domestic source. The demand for swabs has dramatically increased worldwide, and domestic supply is rapidly increasing. Earlier this year, however, there were significant shortages of the supply of swabs for COVID-19 testing in the U.S. and around the world.
  - In an effort to speed the supply of swabs manufactured internationally to the U.S., the Air Force initially airlifted swabs. As of April 3, the Air

events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-antigen-test-help-rapid-detection-virus-causes.

Force had made nine flights between the U.S. and Italy to deliver more than 4 million swabs to the U.S.[8]

- In April, the FDA announced an expansion of COVID-19 testing supply options when U.S. Cotton changed production of its existing Q-tip swabs at an Ohio factory to a swab that could be used for specialized COVID-19 testing; the company can manufacture 3 million swabs per week, and expects to scale up to manufacture 150 million swabs by the end of the year.[9] Also in April, the Department of Defense invested $75.5 million in Defense Production Act (DPA) Title 3 funding to help domestic swab supplier, Puritan, produce an additional 20 million to 40 million swabs per month.[10] These actions have dramatically increased the supply of domestically manufactured swabs for COVID-19 testing.

- The FDA has approved additional types of swabs for use when validated by an individual lab with the specific test being used, which further expanded swab supply.

- University laboratories and domestic companies started manufacturing and have also been producing high quality swabs using 3-D printing technology.[11] Northwell Health and the University of South Florida in partnership are designing and manufacturing nasal swabs using 3-D printers from Formlabs Inc. Northwell Health can print up to 3,000 swabs per day, and Formlabs can print up to 100,000 swabs per day at a facility in Ohio.[12]

- In addition, the FDA granted an EUA for a saliva-based test to detect active infection.[13] In contrast to respiratory samples, saliva samples do not require swabs and transport media.

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[8] U.S. Department of Defense, *Air Force to Make 9th Flight to Deliver Testing Swabs* (Apr. 3, 2020) *available at* https://www.defense.gov/Explore/News/Article/Article/2136285/air-forces-to-make-9th-flight-to-deliver-testing-swabs/.

[9] Dan Diamond, *How a 96-hour project helped Trump's team reverse its testing debacle*, POLITICO (May 5, 2020), *available at* https://www.politico.com/news/2020/05/05/coronavirus-trump-testing-partnership-236313; Lynna Lai, *Cleveland-based U.S. Cotton tackles swab shortage for COVID-19 tests*, WKYC (Apr. 23, 2020), *available at* https://www.wkyc.com/article/news/health/coronavirus/cleveland-based-us-cotton-tackles-swab-shortage-for-covid-19-tests/95-be469714-dcb0-499a-8c07-445e3460d1a4.

[10] U.S. Department of Defense, *DOD Details $75 Million Defense Production Act Title 3 Puritan Contract* (Apr. 29, 2020), *available at* https://www.defense.gov/Newsroom/Releases/Release/Article/2170355/dod-details-75-million-defense-production-act-title-3-puritan-contract/; Puritan, *Puritan Medical Products to Double COVID-19 Swab Production with New Factory* (May 4, 2020), *available at* https://www.puritanmedproducts.com/news-and-events/news/post/Press-Release-Puritan-COVID-Swab-New-Factory).

[11] Sara Castellanos and Agam Shah, *With Medical Equipment in Short Supply, 3-D Printing Steps Up in Coronavirus Crisis*, THE WALL STREET JOURNAL (Mar. 31, 2020), *available at* https://www.wsj.com/articles/with-medical-equipment-in-short-supply-3-d-printing-steps-up-in-coronavirus-crisis-11585686310.

[12] *Id.*

[13] U.S. Food and Drug Administration, *Emergency Use Authorizations*, https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd (last visited May 29, 2020).

- The FDA expanded the supply of transport media by allowing the use of saline, which is more readily available than the solution typically used.[14]

- In addition, and in support of the White House Task Force's testing initiative, FEMA is supporting the procurement of specimen collection supplies to supplement the supplies states and health care providers are procuring from the private market. As of May 29, FEMA has procured and delivered 9.9 million swabs and 5.5 million units of media so far in the month of May.[15]

- With respect to collection tubes, in April, the White House Task Force partnered with the Oak Ridge National Laboratory, a U.S. Department of Energy laboratory based in Tennessee, to manufacture 40 million collection tubes per month.[16]

- U.S. scientists in academic institutions have started manufacturing reagents. For example, some states such as Virginia and New York have partnered with local academic institutions to be able to manufacture reagents needed for their own tests. The University of Virginia created a test in March that ran 500 tests per day. By creating their own supplies and acquiring two additional machines, they plan to increase testing capacity to 3,000 tests per day by early June.[17]

- The supply of reagents and transport media have been a limiting factor in increasing the volume of testing in the U.S. However, the supplies of reagents, including RNA extraction, for U.S. testing are improving. Recently, the issues have been more logistical rather than lack of an adequate supply. Federal government research has indicated that there will be at least 28 million testing reagents available in the U.S. market in May, with that number growing substantially over the coming months.[18]

- Once the current phase of the pandemic has passed, it will be critical to restock and maintain the needed level of supplies for diagnostic testing in anticipation of an increase in COVID-19 cases in the fall.

    - Congress and the Executive Branch should also consider what diagnostic tests and testing supplies, and at what level, should be included in the Strategic National Stockpile. Prior to the COVID-19 pandemic, these supplies were not included in the SNS nor was there an explicit

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[14] Matthew Herper, *To speed coronavirus testing, FDA greenlights a new type of nasal swab*, STAT NEWS (Apr. 16, 2020), *available at* https://www.statnews.com/2020/04/16/fda-changes-coronavirus-testing-swabs/.
[15] U.S. Department of Homeland Security, FEMA, *Daily Briefing Points* (May 29, 2020) (on file with Committee).
[16] Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing, The White House (Apr. 20, 2020), *available at* https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-29/.
[17] Katherine Knott, *UVA working to rapidly increase virus testing capacity*, THE DAILY PROGRESS (May 2, 2020), *available at* https://www.dailyprogress.com/news/local/uva-working-to-rapidly-increase-virus-testing-capacity/article_13536bc8-45fe-5d6e-81d2-e7af4bba813b.html.
[18] U.S. Department of Health and Human Services, Report to Congress, COVID-19 Strategic Testing Plan 21-22 (May 24, 2020).

requirement to do so.[19] The recently enacted CARES Act, through Section 3102, makes explicit the requirement that diagnostic tests be included in the SNS.[20]

- In addition, diagnostic testing capacity is interdependent on the supply of PPE for individuals collecting and processing the sample where needed, the amount of time required to ship and process the sample, and testing supplies.
    - PPE supplies needed for individuals collecting and processing a sample for diagnostic testing include gloves, masks and face shields, gowns or laboratory coats, and respirators when appropriate.
    - While not the focus of this work product, efforts have also been made to increase the supply of PPE. Among other initiatives:
        - Project Air Bridge has been used to expedite delivery of PPE for wholesale distributors from overseas factories.
        - In April, the U.S. Department of Health and Human Services (HHS) announced an agreement with DuPont to expedite the delivery of Tyvek coveralls, with the anticipated delivery of 2.25 million coveralls over the following five weeks with an option to continue purchasing up to a total of 4.5 million. The Tyvek suits are arranged to be delivered to the SNS for further distribution.[21]
        - The Defense Logistics Agency awarded a contract to Battelle for 60 critical care decontamination system units for the sanitation and reuse of N95 respirators.[22]

C. <u>What is the volume of testing for active infections in the U.S. that can be achieved by the fall for a potential second wave?</u>

- Diagnostic tests are an essential first step to understanding the magnitude of a potential fall resurgence of COVID-19. Now that numerous diagnostic tests have been developed and continue to be developed, the challenge will be assuring a volume of diagnostic testing that meets public health needs, while maintaining accuracy.

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[19] Email from HHS ASPR Legislative Staff to Minority Staff (May 26, 2020); U.S. Department of Health and Human Services, Report to Congress, COVID-19 Strategic Testing Plan (May 24, 2020) 42 ("For the first time, the Strategic National Stockpile will be stockpiling testing supplies.").

[20] Coronavirus Aid, Relief, and Economic Security Act, Pub. L. 116-136 (2020).

[21] U.S. Department of Health and Human Services, *HHS to Provide Millions of TYVEK Protective Suits for U.S. Healthcare Workers* (Apr. 8, 2020), *available at* https://www.hhs.gov/about/news/2020/04/08/hhs-provide-millions-tyvek-protective-suits-us-healthcare-workers.html.

[22] U.S. Department of Defense, *DOD Contract for 60 N95 Critical Care Decontamination Units* (Apr. 13, 2020) *available at* https://www.defense.gov/Newsroom/Releases/Release/Article/2148352/dod-contract-for-60-n95-critical-care-decontamination-units-415m-contract-each/.

- In addition, serology or antibody testing to detect past infections can further complement diagnostic testing.

- The Federal government recommends all states to have an objective of testing a minimum of two percent of their population in May and June 2020, pending additional new data on infections and impact of reducing mitigation.[23]

- In the May 24, 2020, COVID-19 Strategic Testing Plan report provided by HHS to Congress, the Federal government predicted the nation will be capable of performing at least 40 million to 50 million tests per month by September, which includes approximately 25 million point of care tests, including new COVID-19 antigen tests.[24]

- As of May 29, more than 16 million coronavirus tests have been conducted in the U.S. to date.[25]

- During the seven-day period from May 22 through May 28, 2020, an average of 368,900 diagnostic tests for COVID-19 were performed each day; the total number of diagnostic tests performed was more than 2.58 million.[26] More than 441,000 tests were performed on May 25, 2020.[27] This is a rapid acceleration of diagnostic testing capacity from just a few months ago. In early March, only a few thousand tests were performed each day, and has been growing steadily at 25 percent to 30 percent per week.[28]

- According to Dr. Deborah Birx, in a May 7, 2020, interview on *CNN*, 2.5 percent of the U.S. population has already been tested, with an expected additional 0.5 percent per week moving forward.[29] If such a trend were maintained for the next few months, about 10 percent of the U.S. population would be tested by September.

- The White House Coronavirus Task Force identified over 5,000 machines in 700 labs currently available in the U.S.;[30] the equipment in state, private, and commercial settings is able to process about 2.14 million tests per day, which represents equipment capacity output without consideration for the availability of

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[23] U.S. Department of Health and Human Services, Report to Congress, COVID-19 Strategic Testing Plan 17 (May 24, 2020).
[24] *Id* at 19.
[25] The COVID Tracking Project, https://covidtracking.com/data (last accessed May 29, 2020).
[26] *Id.*
[27] *Id.*.
[28] U.S. Department of Health and Human Services, Report to Congress, COVID-19 Strategic Testing Plan 10 (May 24, 2020).
[29] *Coronavirus testing in the US should surpass 8 million this week, Birx says*, CNN (May 7, 2020), *available at* https://www.cnn.com/world/live-news/coronavirus-pandemic-05-07-20-intl/h_1af899d5c85b6580cf2ad3fbfc484983.
[30] Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing, The White House (May 11, 2020), *available at* https://www.whitehouse.gov/briefings-statements/remarks-president-trump-press-briefing-covid-19-testing/.

testing resources needed to achieve the testing capacity, such as supplies for specimen collection, trained staff and chemical reagents.[31]

- The drive-through testing program continues to expand with use of provider-administered swab tests and includes various retail locations. As of May 8, 2020, nearly 950 drive-through testing sites were identified throughout all 50 states and the District of Columbia.[32]

- Due to the progress made by the states and the federal government in ramping up testing over the last few months and expected additional progress in the coming weeks, the U.S. could expect to test at multiple times the current level by fall 2020. In a recent hearing, Admiral Brett Giroir testified that by September, the U.S. may be able to test up to 50 million people per month for COVID-19 or about 1.66 million tests per day. Even if that goal were missed by almost 40 percent, about one million tests per day would still be conducted in the U.S.[33] This estimate takes into account the availability of supporting supplies, and does not factor in the potential added volume of testing that would be contributed by antigen testing, antibody testing, and any new types of molecular diagnostic testing, including those that do not require transport media and swabs. Thus, a one-million-tests-per-day estimate could substantially understate the level of COVID-19 testing that could be available in the U.S. by the fall.

- At more than a million tests a day, the U.S. would exceed the Harvard Global Health Institute's recommendation of 900,000 tests per day to contain the outbreak.[34]

- At more than a million tests a day, there would be more than enough capacity to test high-priority categories. Resolve to Save Lives, a public health initiative headed by former Director of the Centers for Disease Control and Prevention (CDC) Tom Frieden, calculated the number of highest-priority people who need tests, and determined a lower bound number of 350,000 to 700,000 tests per day. This includes high-risk patients with COVID-19 symptoms and any sick hospital workers, public safety officers, prisoners, or nursing home residents and their symptomatic contacts.[35]

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[31] Mike DeBonis, Chris Mooney, and Juliet Eilperin, *White House issues coronavirus testing guidance that leaves states in charge*, THE WASHINGTON POST (Apr. 27, 2020), *available at* https://www.washingtonpost.com/politics/white-house-issues-coronavirus-testing-guidance-that-leaves-states-in-charge/2020/04/27/c465cc9c-88a2-11ea-8ac1-bfb250876b7a_story.html.

[32] Mui, Katie, *Where Can I Get a Drive-Thru Coronavirus (COVID-19) Test Near Me?*, GOODRX (May 8, 2020), *available at* https://www.goodrx.com/blog/drive-thru-coronavirus-testing-near-me/.

[33] Hearing before U.S. Senate Health, Labor, Education, and Pensions Committee, COVID-19: Safely Getting Back to Work and Back to School (May 12, 2020), *available at* https://www.help.senate.gov/hearings/covid-19-safely-getting-back-to-work-and-back-to-school.

[34] UPI, *900,000 daily COVID-19 tests needed to contain the U.S. outbreak, Harvard experts say* (May 7, 2020), *available at* https://www.upi.com/Top_News/US/2020/05/07/900000-daily-COVID-19-tests-needed-to-contain-US-outbreak-Harvard-experts-say/1521588869822/.

[35] Jessica McDonald, *How Many COVID-19 Tests Are 'Needed' to Reopen?*, FactCheck (May 8, 2020), *available at* https://www.factcheck.org/2020/05/how-many-covid-19-tests-are-needed-to-reopen/.

- To put the improved level of U.S. testing in context, South Korea has been touted as a success story in rolling out its testing program for COVID-19 quickly and successfully halting its outbreak. In March 2020, South Korea reportedly had the capacity to test about 20,000 people a day in a country with a population of about 51 million.[36] The U.S. has a population of about 328 million, which is about 6.4 times the population of South Korea. To achieve a similar level of testing as South Korea for its population, the U.S. would need to test 128,000 people a day. The U.S. has consistently tested more than 128,000 people per day since early April, recently surpassing 440,000 tests in a single day.[37] This daily level is expected by government officials and industry to continue to increase substantially throughout the summer months. Assuming the number of cases substantially subsides during the summer, the U.S. testing capacity to combat a second outbreak should be expected to greatly exceed South Korea's capacity at the time it halted its first outbreak.

- Capacity will continue to increase with the development of rapid point-of-care diagnostics, such as those developed by Abbott Diagnostics and Cepheid, as well as additional development and full use of diagnostics that can be run on high-throughput laboratory machines. Although overall testing capacity is increased with point-of-care testing, an additional and more accurate PCR test may be necessary when point-of-care tests return false negative results.

D. <u>In terms of the fall response for an expected second wave, what should be the strategy for testing for active infections?</u>

- The U.S. testing strategy should be "smart" testing. It is not possible nor necessary to test everybody in the U.S. every day. Some think tanks have suggested we need extremely high levels of testing (20 million to 30 million tests per day) to reopen the economy. The HHS Strategic Testing Plan noted that one estimate calling for extremely high levels of testing was based on unreasonable assumptions about the sensitivity of the test, hospitalization rates, and the number of days to recovery.[38] When these assumptions are corrected, the simulation model's testing level comes down to more realistic levels.[39] Relying on estimates of unrealistic testing is not only unnecessary, but it provides inaccurate context to the public and policymakers about what is the appropriate level of testing. Further, no level of testing, even at a frequency of every day, would necessarily detect asymptomatic cases before any transmission. Thus, the focus should be on how to best leverage a vastly increased testing capacity with quality tests.

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[36] *Upfront, Testing Times: Why South Korea 's COVID 19 strategy is working*, AL JAZEERA (Mar. 21, 2020), *available at* https://www.aljazeera.com/programmes/upfront/2020/03/testing-times-south-korea-covid-19-strategy-working-200320051718670.html; Laura Bicker, *Coronavirus in South Korea: How 'trace, test and treat' may be saving lives*, BBC (Mar. 12, 2020), *available at* https://www.bbc.com/news/world-asia-51836898.
[37] The COVID Tracking Project, https://covidtracking.com/data/us-daily (last visited May 29, 2020).
[38] U.S. Department of Health and Human Services, Report to Congress, COVID-19 Strategic Testing Plan 13 (May 24, 2020).
[39] *Id.*

- It should be assumed there will be a much greater volume of testing, but prioritization of testing will still be needed. As the U.S. has achieved a greater level of testing, and continues to increase, there should be an ability to meet prioritized testing needs while also reserving some capacity for screening populations to detect asymptomatic cases.

- In general, the strategy for COVID-19 testing has been to prioritize vulnerable persons at the highest risk of infection.[40] In terms of the fall response, one top priority should continue to be to test every person who has symptoms of COVID-19.[41]

- Another top priority should be testing nursing home and assisted living residents and staff, whether symptomatic or not. Nursing homes and other congregate living centers account for more than 40 percent of COVID-19 deaths nationally, even though residents at these facilities represent a fraction of a percent of the population.[42]

    - A national testing strategy prioritizing required testing at nursing homes and other congregate living centers would help resolve the inconsistent approaches of states in addressing issues at these facilities. Nursing homes in California, Michigan, New York, and New Jersey were required to accept COVID-19 positive patients, and New York prohibited nursing homes from requiring testing prior to admission or readmission.[43] In May, Michigan, New York and New Jersey changed their orders to no longer require nursing home admission and California offered financial reimbursement to assisted living facilities in exchange for housing COVID-positive patients.[44]

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[40] This is based on the CDC guidance and similar guidance from state health departments.

[41] Dan Mangan, *South Korea's broad coronavirus testing strategy could fatten curve in some US areas, expert says* (Apr. 7, 2020), *available at* https://www.cnbc.com/2020/04/07/coronavirus-south-korea-testing-could-flatten-pandemic-curve-in-us-areas.html.

[42] Avik Roy, *The Most Important Coronavirus Statistic: 42% of U.S. Deaths are from 0.6% of the Population,* Forbes (May 26, 2020) *available at* https://www.forbes.com/sites/theapothecary/2020/05/26/nursing-homes-assisted-living-facilities-0-6-of-the-u-s-population-43-of-u-s-covid-19-deaths/#281ca10574cd.

[43] Kim Barker and Amy Julia Harris, *Playing Russian Roulette': Nursing Homes Told to Take the Infected*, N.Y. TIMES (May 7, 2020), https://www.nytimes.com/2020/04/24/us/nursing-homes-coronavirus.html; Tobias Hoonhout, *Order Forcing Nursing Homes to Take Covid Patients Scrubbed* from State Website, NATIONAL REVIEW (May 26, 2020) https://www.nationalreview.com/news/cuomo-coronavirus-order-forcing-nursing-homes-to-take-covid-19-patients-scrubbed-from-new-york-state-website/; The Detroit News, *Editorial: Whitmer order endangers nursing homes; end it now*, Detroit News (May 19, 2020) *available at* https://www.detroitnews.com/story/opinion/editorials/2020/05/20/editorial-whitmer-order-endangers-nursing-homes-end-now/5220929002/.

[44] Denise Merna Adika and Lina Goto, *New York and New Jersey Require COVID-19 Staff Testing at Long-Term Care Facilities,* NATIONAL LAW REVIEW (May 15, 2020) *available a*t https://www.natlawreview.com/article/new-york-and-new-jersey-require-covid-19-staff-testing-long-term-care-facilities; Annie Sciacca, *Coronavirus: Pay for stay? State agency offers cash incentive if board and care homes take in COVID-19-positive seniors from hospitals*, MERCURY NEWS (May 4, 2020) *available at* https://www.mercurynews.com/2020/05/04/california-offers-senior-care-facilities-contracts-to-accept-covid-19-patients/; Michigan Executive Order 2020-95, COVID-19, (May 20,2020) *available at* https://www.michigan.gov/whitmer/0,9309,7-387-90499_90705-529855--,00.html.

- In contrast, Connecticut and Massachusetts designated certain facilities for COVID patients.[45] Utah created nursing home testing strategies that included mobile unit outreach testing to all state facilities, with special emphasis on rural long term care facilities, and, with support of the hospital and health care associations, developed a testing protocol for patients prior to transfer from hospitals to long term care facilities.[46]

- On May 18, 2020, the Centers for Medicare and Medicaid Services (CMS) published recommendations that nursing home facilities have COVID-19 testing plans informed by the CDC and, at minimum, should consider testing capacity for (1) all residents to receive a single baseline COVID-19 test; (2) all residents to be tested if an individual with COVID-19 symptoms presents or if a staff member tests positive; (3) weekly re-testing of all residents until all test negative; and (4) all nursing home staff, including vendors and volunteers, to receive a baseline test, with weekly staff re-testing. CMS also recommends that nursing homes make arrangements with laboratories for test processing.[47]

- States should have clear plans in place to protect the safety of nursing home residents through regular testing and other means, and limit exposure of nursing home residents to known COVID-19 patients. States that have adopted policies requiring that nursing homes accept COVID-19 positive or suspected positive patients should strongly reconsider these policies and, if not, provide public plans for how they will protect the safety of residents not infected or presumed to be infected with COVID-19.

- The next priority for COVID-19 testing, as identified by public health officials, should be persons in high-risk populations who have some symptoms, but do not meet the clinical definition of being symptomatic, or even those who have no symptoms. Persons identified as high priority for testing by public health officials are: hospitalized patients; health care facility workers; workers in congregate living settings; first responders; residents in long-term care facilities or other congregate living settings (including correctional and detention facilities and shelters); persons who come from racial and ethnic minority groups disproportionately affected by adverse COVID-19 outcomes; and workers in meat and poultry packing plants. In addition, this high-priority category could be expanded to include

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[45] Kim Barker and Amy Julia Harris, '*Playing Russian Roulette': Nursing Homes Told to Take the Infected*, N.Y. TIMES, (May 7, 2020), *available at* https://www.nytimes.com/2020/04/24/us/nursing-homes-coronavirus.html.
[46] Centers for Medicare and Medicaid Services, *Toolkit on State Actions to Mitigate COVID-19 Prevalence in Nursing Homes*, (May 2020) *available at* https://www.cms.gov/files/document/covid-toolkit-states-mitigate-covid-19-nursing-homes.pdf.
[47] Centers for Medicare and Medicaid Services, *Nursing Home Reopening Recommendations for State and Local Officials* (May 18, 2020), *available at* https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfs-states-and-regopolicy-and/nursing-home-reopening-recommendations-state-and-local-officials.

workers in all 16 critical infrastructure sectors as set out by HHS in its strategic plan for testing.[48]

- The main challenge for the fall response is detecting asymptomatic cases since pre-symptomatic or asymptomatic patients can transmit COVID-19. As a result, undetected cases play a major role in the transmission of COVID-19. Between 12 percent and 23 percent of infections may be caused by asymptomatic or pre-symptomatic transmission.[49] Models suggest up to 86 percent of early COVID-19 cases in China were undetected, and these infections were the source for 79 percent of reported cases.[50]

- A testing strategy focused on symptomatic or high-risk persons should be coupled with some level of targeted population screening especially in high-risk populations in an attempt to detect asymptomatic cases.

- Two options for mass screening are the use of pooled sampling and random sampling. The concept of pooling diagnostic tests and running them together in one batch will help optimize testing capacity. If a pooled sample tests negative, everyone in the pool is negative. If it is positive, the members of the pool can be tested individually.[51] For example, former FDA Commissioner Scott Gottlieb has noted that polymerase chain reaction (PCR) testing platforms can be used for mass screening by pooling many patients' samples, such as in a workplace and testing them all at once to see if anyone in the group is infected.[52] Pooled sampling was recently used by Stanford Medical School in examining the prevalence rate in the San Francisco Bay Area. Combining samples from several people at one time allowed scientists to estimate the prevalence of the disease in the San Francisco Bay Area while conserving scarce testing resources.[53]

    - Judicious and targeted use of random sampling could also help detect what percentage of the population has COVID-19 and provide better insight into the

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[48] *Id.* at 27

[49] Z. Du et al., *The serial interval of COVID-19 from publicly reported confirmed cases*, medRxiv (Mar. 13, 2020), *available at* https://www.medrxiv.org/content/medrxiv/early/2020/03/13/2020.02.19.20025452.full.pdf; Liu, Y.; Funk, S.; Flasche, S., *The Contribution of Pre-symptomatic Transmission to the COVID-19 Outbreak*, CCMID Repository, London School of Hygiene and Tropical Medicine (Feb. 2, 2020), *available at* https://cmmid.github.io/topics/covid19/control-measures/pre-symptomatic-transmission.html.

[50] Li, R., et al., *Substantial undocumented infection facilitates the rapid dissemination of novel coronavirus (SARS-CoV2)*, SCIENCE (Mar. 16, 2020), *available at* https://science.sciencemag.org/content/sci/early/2020/03/13/science.abb3221.full.pdf.

[51] Ezekiel J. Emanuel and Paul M Romer, *Without more tests, America can't reopen*, THE ATLANTIC (Apr. 18, 2020), *available at* https://www.theatlantic.com/ideas/archive/2020/04/were-testing-the-wrong-people/610234/.

[52] Scott Gottlieb, *The Cruel Covid 'New Normal'*, THE WALL STREET JOURNAL (May 4, 2020), *available at* https://www.wsj.com/articles/the-cruel-covid-new-normal-11588526503.

[53] Krista Conger, *Testing pooled samples for COVID-19 helps Stanford researchers track early viral spread in Bay Area*, STANFORD MEDICINE (Apr. 7, 2020), *available at* https://med.stanford.edu/news/all-news/2020/04/testing-pooled-samples-to-track-early-spread-of-virus.html.

virus' lethality.[54] As more testing data is obtained, the overall lethality rates in CDC data are dropping as more mild cases are detected, thus increasing the denominator of total number of infections that deaths would be measured against.

E. How should states and the federal government best manage and leverage existing testing resources, and expanding testing resources?

- States, working with the federal government, should determine a strategy that utilizes all available testing resources, including rapid point-of-care diagnostic testing, high-throughput laboratory testing, and antibody testing.

- States should implement and maintain these strategies going into the fall.

- An effective testing strategy should address the necessary frequency of testing, risk levels for different populations, identifying asymptomatic and mild cases through surveillance, and contact tracing, among other issues.

- Public health organizations have set an objective that the proportion of positive test results (percent positive) should be 10 percent or less.[55] The basis for this metric is that if 20 percent or 30 percent of the tests are positive, it is likely many positives are being missed as well as their contacts. If only 10 percent are positive (or less), then testing is likely enough to assure broad coverage of the population. States are largely reaching positivity rate goals. Disaggregated data shows that 41 states have already achieved the 10 percent positive or lower threshold (7-day averages), with the remaining states and the District of Columbia continuing to improve on a daily basis as testing increases.[56]

- The federal government's support for states to get more testing supplies has been in response to state needs. At the state level, it appears the main challenge has been obtaining more testing supplies rather than increasing laboratory testing capacity. It has been reported that available laboratory testing capacity in the U.S. is not being fully utilized due to a shortage of testing component supplies, staffing shortages, enough tests are not being ordered to fully utilize the capacity, and/or because people who are mildly symptomatic are instructed to stay home and not seek testing or health care, among other factors.

- An effective testing strategy in one state may not be effective in another state. Similarly, a strategy for one region of a state may not be effective in other regions within that state. Testing strategies should address regional variances where appropriate, for example, the testing strategy for New York City might be different

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[54] Lisa Boothe, *How deadly is the coronavirus*, THE HILL (Apr. 4, 2020), *available at* https://thehill.com/opinion/healthcare/491021-how-deadly-is-the-coronavirus.
[55] U.S. Department of Health and Human Services, Report to Congress, COVID-19 Strategic Testing Plan 14 (May 24, 2020).
[56] *Id*. at 15.

than a strategy for up-state New York. A one-size fits all approach to testing is not the right strategy.

- The federal government provides strategic guidance on the best use of available testing technologies, approves new tests to expand capacity, and provides expert guidance to assist in rapid response to localized outbreaks in industries providing critical infrastructure.[57]

    - It will be important for states to accurately and continuously monitor their testing supply chain, testing supplies, testing equipment capacity, personnel and testing demand. States need to track testing results and have reliable data collection, reporting and communication methods in or near real time. Without accurate data, existing testing resources may not be properly used.

    - Local jurisdictions can consider multi-jurisdictional purchasing arrangements to leverage volume and increase purchasing power of test supplies.

- The federal government and states can best leverage and expand testing resources through ongoing data collection and communication that monitors demand signals and supply needs in geographic locations to strategically align laboratory testing supplies and capacity with anticipated needs.

- The Community-Based Testing Sites (CBTS) program, originally established by the White House Task Force, offers a high-impact model for successful collaboration between the federal government, states, local public health agencies, health care systems, and commercial partners to expand critical testing capacity for symptomatic and asymptomatic individuals, while sharing best practices for testing sample collection and preserving PPE.[58] Out of 41 original sites, 14 continue to operate as federal run sites, 20 have transitioned to state management, and seven have closed in consultation with the states.[59] Many states have started transitioning the programs to state control to allow greater flexibility in testing and reporting and other states have implemented testing sites based on the CBTS model.[60] In addition, through public-private partnerships with pharmacy and retail companies, there are currently 415 sites conducting testing.[61] As of May 28, more than 215,000 test samples have been processed at federally run Community Based Testing Sites and more than 412,000 samples have been processed at public-private partnership testing sites.[62]

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[57] U.S. Department of Homeland Security, FEMA, *Federal Support to Expand Testing Efforts* (May 5, 2020), *available at* https://www.fema.gov/news-release/2020/05/05/federal-support-expand-national-testing-capabilities.
[58] *Id.*
[59] U.S. Department of Homeland Security, FEMA, *Daily Briefing Points* (May 29, 2020) (on file with Committee).
[60] U.S. Department of Homeland Security, FEMA, *Option to Transition Federal Community-Based Testing Sites To State Management* (Apr. 9, 2020), *available at* https://www.fema.gov/news-release/2020/04/09/option-transition-federal-community-based-testing-sites-state-management.
[61] U.S. Department of Homeland Security, FEMA, *Daily Briefing Points* (May 29, 2020) (on file with Committee).
[62] *Id.*

- Under the White House plan to improve laboratory access to testing platforms and supplies, the CDC will launch a community protection team program intended to focus state and local governments on key public health tasks, such as laboratory testing, surveillance, and contact tracing.[63]

F. What is the importance and role of antibody testing in a comprehensive testing scheme?

- Antibody tests are an important element of a comprehensive testing scheme. Antibody testing is needed to determine the full scope of an outbreak as well as assessing the potential population immunity to the virus To understand the role of antibody testing in a comprehensive testing scheme, it is important to understand how antibody tests work, how they are different from diagnostic tests, and the limitations of antibody tests. These characteristics of antibody tests are discussed below before a broader discussion of the role of antibody testing in a comprehensive testing scheme.

- Antibody tests, also commonly referred to as serology tests, are simple blood tests that can detect whether a person has developed antibodies to the COVID-19 virus.[64] A person develops antibodies to a virus when a person is exposed to the virus and their immune system was robust enough to launch an antibody-forming immune response.[65]

- Antibody tests must be differentiated from diagnostic tests that identify active infections and should not be used as the sole basis to diagnose an active infection for COVID-19.[66] Rather than detecting the virus itself, antibody tests detect the body's immune response to the infection caused by COVID-19.[67] According to the CDC, it may take an individual one to three weeks after infection to develop antibodies.[68]

- As of May 4, 2020, FDA must review commercial manufacturers' serology tests. More specifically, in FDA's revised May 2020 guidance, FDA: (1) noted that it expects commercial manufacturers of antibody tests to submit EUA requests, with their validation data, within 10 business days from the date they notified the FDA of their validation testing or from the date of the policy, whichever is later; and (2)

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[63] *White House Unveils National COVID-19 Testing Plan, Adopting Many ASCP Recommendations*, American Society for Clinical Pathology (Apr. 27, 2020), *available at* https://www.ascp.org/content/news-archive/news-detail/2020/04/27/white-house-unveils-national-covid-19-testing-plan-adopting-many-ascp-recommendations.
[64] Cynthia Demarco, *7 things to know about COVID-19*, MD Anderson Cancer Center (Apr. 22, 2020), *available at* https://www.mdanderson.org/publications/cancerwise/7-things-to-know-about-coronavirus-COVID19-antibody-testing.h00-159381156.html.
[65] *Id.*
[66] U.S. Food and Drug Administration, *EUA Authorized Serology Test Performance* (May 6, 2020), *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance.
[67] *Id.*
[68] Centers for Disease Control and Prevention, *Testing for COVID-19* (May 1, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html.

provided specific performance threshold recommendations for specificity and sensitivity for all serology test developers.[69]

- High-complexity laboratories that have been issued a CLIA certificate by CMS can legally develop LDTs, but they are encouraged to seek authorization through an EUA.[70]

- The May 2020 policy update revised the Agency's earlier policy on antibody tests; the earlier policy provided a higher level of flexibility for antibody tests than for molecular tests. FDA updated its policy on antibody tests because, according to the Agency, the careful balancing of risks and benefits for antibody tests had changed between March 16, 2020 and May 4, 2020, as FDA authorized more antibody tests and more validation data became available.[71]

  - When updating its policy, FDA noted that in mid-March it was critical for FDA to provide regulatory flexibility to antibody test developers to promote the early availability of antibody tests. In the March 16, 2020 policy, FDA stated: "[w]e recognize that serology tests are less complex than molecular tests and are solely used to identify antibodies, which limits their effectiveness for diagnosis; however, as stated in the updated guidance, the FDA does not intend to object to the distribution and use of serology tests to identify antibodies to COVID-19 where the test has been validated, notification is provided to the FDA, and warning statements are included with the tests, for example, noting the test has not been reviewed by the FDA and results from antibody testing should not be used as the sole basis to diagnose or exclude COVID-19 infection or to inform infection status."[72]

  - Unfortunately, since the March 16, 2020, policy was issued, FDA identified bad actors marketing fraudulent test kits and identified instances where commercial serology tests have been promoted inappropriately.[73] FDA has taken appropriate action against these actors, and the Agency believes that the updated May 4, 2020, guidance will help protect against fraud.

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69 Anand Shah, M.D., Deputy Commissioner for Medical and Scientific Affairs, and Jeff Shuren, M.D., Director, Center for Devices and Radiological Health, *Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy* (May 4, 2020), *available at* https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy.

70 *Id.*

71 *Id.*

72 U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics* (Mar. 16, 2020), *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help.

73 Anand Shah, M.D., Deputy Commissioner for Medical and Scientific Affairs, and Jeff Shuren, M.D., Director, Center for Devices and Radiological Health, *Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy* (May 4, 2020), *available at* https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy.

- As of May 29, 2020, FDA had approved 12 antibody tests under an individual EUA;[74] as of May 4, 2020, over 200 antibody tests were currently the subject of a pre-EUA or EUA review.[75]

    - FDA maintains a webpage with summaries of the expected performance of the 12 tests that the Agency has authorized based on the information FDA reviewed when determining whether to approve an EUA for these tests.[76]

    - The performance of antibody tests is described by a test's "sensitivity," or the ability to identify those individuals with antibodies to COVID-19 (true positive rate), and a test's "specificity," or the ability to identify those individuals without antibodies to COVID-19 (true negative rate).[77] The sensitivity and specificity of each of the 12 tests that have received an EUA are included on the FDA's webpage.[78]

    - All antibody tests will return some false positive and some false negative results.[79] The tests are therefore also described by the test's Positive and Negative Predictive values (PPV and NPV) which help individuals interpreting the test evaluate how likely it is that a person who receives a positive result from a test truly does have antibodies to COVID-19 and how likely it is that a person who receives a negative result from a test truly does not have antibodies to COVID-19.[80] The PPV and NPV values of each of the tests that have received an EUA are included on the FDA's webpage.[81]

- FDA has also worked with the CDC, National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA) to develop capacity at the National Cancer Institute (NCI) for the NCI to evaluate commercially available antibody tests.

    - According to NCI, "the main goal of this effort is to determine whether available antibody tests are accurate. Meaning, does a given test pick up SARS-CoV-2 antibodies when they are present in someone's blood, and

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[74] U.S. Food and Drug Administration, *Coronavirus (Covid-19) Update: Daily Roundup* (May 29, 2020), *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-may-29-2020

[75] *Id.*; U.S. Food and Drug Administration, *Coronavirus (Covid-19) Update: Daily Roundup* (May 14, 2020), *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-may-14-2020.

[76] U.S. Food and Drug Administration, *EUA Authorized Serology Test Performance* (May 6, 2020), *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance.

[77] *Id.*

[78] *Id.*

[79] *Id.*

[80] *Id.*

[81] *Id.*

not give a signal when they aren't."[82] Results from NCI's validation studies are provided to FDA on a rolling basis—as of May 4, the NCI had shared validation data with the FDA from 13 test kits.[83]

- A secondary goal of the effort at NCI is also to develop standards for SARS-CoV-2 serology tests.[84]

- A positive antibody test only confirms that a person currently has or has had a COVID-19 infection.[85] We do not know whether a positive COVID-19 antibody test result also means that a person has full or partial immunity to COVID-19.[86] Researchers are trying to determine the appropriate use of antibody tests, whether someone who is antibody positive is resistant to reinfection, and if so, how long that person is resistant to reinfection.[87]

- Special attention should be focused on developing a neutralization antibody test.[88] This type of test detects antibodies capable of inhibiting virus replication (or in other words, antibodies that can neutralize virus infection). This test would indicate whether the antibody in fact has a protective effect against the virus.

- As previously mentioned, antibody testing is an important element of a comprehensive testing strategy. Antibody testing is needed to determine the full scope of an outbreak as well as more accurately estimate the fatality and hospitalization rate of those that have been infected to determine its impact on the health care system.

  - The proper use of antibody tests could show the extent of viral spread and help inform decision-making.[89] For example, the CDC has a COVID-19

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[82] National Cancer Institute, *NCI Part of Federal Effort to Evaluate Antibody Tests for Novel Coronavirus* (May 5, 2020), *available at* https://www.cancer.gov/news-events/cancer-currents-blog/2020/covid-19-nci-antibody-testing-review.

[83] *Id.*; Anand Shah, M.D., Deputy Commissioner for Medical and Scientific Affairs, and Jeff Shuren, M.D., Director, Center for Devices and Radiological Health, *Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy* (May 4, 2020), *available at* https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy.

[84] National Cancer Institute, *NCI Part of Federal Effort to Evaluate Antibody Tests for Novel Coronavirus* (May 5, 2020), *available at* https://www.cancer.gov/news-events/cancer-currents-blog/2020/covid-19-nci-antibody-testing-review.

[85] *Id.*

[86] Cynthia Demarco, *7 things to know about COVID-19*, MD Anderson Cancer Center (Apr. 22, 2020), *available at* https://www.mdanderson.org/publications/cancerwise/7-things-to-know-about-coronavirus-COVID19-antibody-testing.h00-159381156.html.

[87] U.S. Food and Drug Administration, *EUA Authorized Serology Test Performance* (May 6, 2020), *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance; Centers for Disease Control and Prevention, *Serology Testing* (May 5, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html.

[88] F. Wu, et al., *Neutralizing antibody responses to SARS-CoV-2 in a COVID-19 recovered patient cohort and their implications*, medRxiv (Apr. 20, 2020), *available at* https://www.medrxiv.org/content/10.1101/2020.03.30.20047365v2.

[89] U.S. Food and Drug Administration, *Important Information on the Use of Serological (Antibody) Tests for COVID-19 – Letter to Health Care Providers* (Apr. 17, 2020), *available at* https://www.fda.gov/medical-

Serology Surveillance Strategy that uses serology testing for surveillance to better understand how many infections with COVID-19 have occurred at different points in time, in different locations, and within different populations in the U.S.[90]

- There are currently multiple serosurveys being conducted across the U.S. to provide more information about disease prevalence. As noted by Dr. Anthony Fauci, Director of NIAID, these studies will "give us a clearer picture of the true magnitude of the COVID-19 pandemic in the United States by telling us how many people in different communities have been infected without knowing it, because they had a very mild, undocumented illness or did not access testing while they were sick."[91]

    - NIH is conducting a serosurvey to determine how many healthy adults have been exposed to the virus that causes COVID-19.[92] The study is recruiting individuals and expects to collect and analyze blood samples from as many as 10,000 volunteers across the country.[93] After individuals attend a virtual clinic visit and complete a health assessment questionnaire, the individuals will submit samples either by having their blood drawn at the NIH Clinical Center at the NIH Bethesda campus or by participating in at-home blood sampling. Neoteryx is supplying the at-home blood collection kits.[94]

    - The Vitalant Research Institute is developing three large serosurvey studies. One of these studies is funded by NIH and is currently being conducted in some major metropolitan areas, including New York City and Seattle, to monitor how many people develop COVID-19 antibodies over time.[95] The study will eventually evolve into a national survey.[96]

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devices/letters-health-care-providers/important-information-use-serological-antibody-tests-covid-19-letter-health-care-providers; Anand Shah, M.D., Deputy Commissioner for Medical and Scientific Affairs, and Jeff Shuren, M.D., Director, Center for Devices and Radiological Health, *Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy* (May 4, 2020), *available at* https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy.

[90] Centers for Disease Control and Prevention, *Serology Surveillance Strategy* (Apr. 28, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/serology-surveillance/index.html.

[91] National Institutes of Health, *NIH begins study to quantify undetected cases of coronavirus infection* (Apr. 10, 2020), *available at* https://www.nih.gov/news-events/news-releases/nih-begins-study-quantify-undetected-cases-coronavirus-infection.

[92] *Id.*

[93] *Id.*

[94] *Id.*

[95] Jon Cohen, *Unprecedented nationwide blood studies seek to track U.S. coronavirus spread*, SCIENCE (Apr. 7, 2020), *available at* https://www.sciencemag.org/news/2020/04/unprecedented-nationwide-blood-studies-seek-track-us-coronavirus-spread#.

[96] *Id.*

        - Early results from an ongoing serostudy conducted by The University of Southern California researchers and county health officials in Los Angeles County found that about 4.1 percent tested positive for antibodies against COVID-19.[97] These preliminary results suggest that "infections from [COVID-19] are far more widespread – and the fatality rate much lower – in L.A. County than previously thought."[98]

    - On May 4, 2020, an NIH-funded study began that examines the incidence of COVID-19 in U.S. children and their family members.[99] For the study, tests for active infection will be performed every two weeks for the child and their family members who are enrolled in the study, and the child's caregiver will complete an online questionnaire. Tests will also be given to any member of the household if there is a likely case of COVID-19 in the home. In addition to tests for active infection, antibody tests will be used at the beginning of the study—and at two weeks, 18 weeks, and 24 weeks after enrollment—and three weeks after a family's first likely case of COVID-19.[100]

- Antibody test results may help determine who qualifies to donate blood that can be used to manufacture convalescent plasma as a possible treatment for patients that are seriously ill from COVID-19.[101]

- There are well-known limitations to serology testing, however, and these limitations must be considered when determining how to deploy serology testing.

    - For instance, as previously discussed, all tests will result in some false positive and negative results. Serology tests may not be as effective in areas with minimal spread of COVID-19 and may result in higher levels of false results in such areas.[102] The FDA therefore recommends that it may sometimes be necessary for some individuals to have two serology tests to generate reliable results.[103]

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[97] Dr. Francis Collins, *The Challenge of Tracking COVID-19's Stealthy Spread*, NIH Director's Blog (Apr. 23, 2020), *available at* https://directorsblog.nih.gov/tag/covid-19-antibody-test/.
[98] Leigh Hopper, *Early antibody testing suggests COVID-19 infections in L.A. County greatly exceed documented cases*, USC University of Southern California (Apr. 20, 2020), *available at* https://news.usc.edu/168987/antibody-testing-results-covid-19-infections-los-angeles-county/.
[99] National Institutes of Health, *Study to determine incidence of novel coronavirus infection in U.S. children begins* (May 4, 2020), *available at* https://www.nih.gov/news-events/news-releases/study-determine-incidence-novel-coronavirus-infection-us-children-begins.
[100] *Id*.
[101] Anand Shah, M.D., Deputy Commissioner for Medical and Scientific Affairs, and Jeff Shuren, M.D., Director, Center for Devices and Radiological Health, *Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy* (May 4, 2020), *available at* https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy.
[102] *Id*.
[103] *Id.*

G. What is the role of the Public Health Laboratory (PHL) system in diagnostic testing, does the system need to be modernized, and what should be the role of PHLs be when a new virus or disease emerges?

- Public health laboratories (PHLs) are the foundation of a national laboratory network system that is on alert around the clock to respond to novel strains of disease, natural disasters, chemical spills, foodborne outbreaks and other health emergencies. PHLs collaborate closely in these efforts with the CDC and other federal agencies including the Federal Bureau of Investigation (FBI), Department of Homeland Security (DHS), and the FDA. They are strategically located in every state, territory and the District of Columbia. PHLs perform limited diagnostic testing and focus on diseases and the health status of population groups.[104]

- PHLs are currently designed to be public incident command centers to convey consistent communications, finance, planning, operations and logistics, and track emerging diseases.[105]

- The PHL system in the U.S. did not have the technology and capacity at the start of the COVID-19 outbreak to provide the type of widescale diagnostic testing required by a pandemic.

- In addition, without federal guidelines to standardize reporting of data, there has been variation in how states have reported data on positive, negative, and pending tests. For example, at one time, Virginia, among several other states, combined both diagnostic and antibody tests in the total number of tests conducted and reported this combined figure to the CDC.[106] States and CDC are moving to a more detailed file format to display viral test data and serologic test data separately in the CDC COVID Data Tracker.[107]

    - Similarly, the COVID-19 Tracking Project recommends improving public reporting of state testing data, including posting all test data (positive, negative, and pending), daily updates with time stamps, data posted on websites, and consistently structured data.[108] This data is important for informing infectious disease modelers and decision-makers.[109]

- PHLs should be modernized to provide access to high-throughput yet flexible testing equipment, similar to what large commercial laboratories have. Funding for such equipment could be provided through the epidemiology and lab capacity grants program.

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[104] Association of Public Health Laboratories, *About Public Health Laboratories* (May 22, 2020), *available at* https://www.aphl.org/aboutAPHL/Pages/aboutphls.aspx.
[105] Centers for Disease Control and Prevention, *Public Health 101 Series: Introduction to Public Health Laboratories*, (Nov. 15, 2018), *available at* https://www.cdc.gov/publichealth101/laboratories.html.
[106] *Id.*
[107] Briefing by CDC for Members and Staff, U.S. House of Representatives (May 22, 2020).
[108] COVID Tracking Project (Mar. 2020), *available at* https://covidtracking.com/.
[109] GAO phone briefing with Committee Staff (Mar. 30, 2020) (notes on file with Committee staff).

- Modernization of the PHLs could expand the number of hospitals reporting to PHLs, expand participation to include urgent care centers, and add predictive analytics and artificial intelligence to uncover changes when a new virus or disease emerges.

- A modernization could expand PHLs' data capacity, exchange, and analytics as they implement next generation bioinformatics tools and build electronic test order and result systems that rapidly share sample status and results, ensure secure, real-time communication of results from the public and private sector to disease detectives, and integrate real time data analysis from multiple sources.[110]

- PHLs should have a cohesive, secure IT infrastructure in order to increase coordination and communication among the PHLs and private sector laboratories and physicians. Such an infrastructure could not only facilitate improved communication, but also better public reporting of state testing data.

- If modernized, PHLs could advance readily available, rapid, and highly sensitive diagnostic tests for use in clinical settings and validate lab-developed tests.[111]

- Congress, the Executive Branch, and the states should consider ways to encourage the submission or more standardized state testing data to the CDC.

- Efforts should also be made by HHS to include PHLs into the new HHS Protect Now platform that currently integrates 187 data sets, including diagnostic testing data, from across the federal, state and local governments, health care facilities, and academia, to help administration officials determine how to mitigate and prevent the spread of COVID-19.[112]

H. <u>What additional types of diagnostics should be developed?</u>

- In addition to the CDC's test developed for the public health laboratories, the private sector and academic laboratories have quickly developed a wide array of diagnostic tests. Molecular diagnostic tests focus on identifying cases where the person has an active infection. Antibody, or serology tests, identify if a person has developed antibodies to the virus.

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[110] *Data: Elemental to Health*, The Association of Public Health Laboratories (Apr. 13, 2020), *available at* https://www.aphl.org/policy/Advocacy_Documents/DSI%20OnePagerI_FINAL%20(002).pdf.
[111] *Id.*
[112] Jackie Gilbert, *HHS COVID "Protect Now" Data Initiative Taps Palantir Technologies*, FEDHEALTHIT (Apr. 28, 2020), *available at* https://www.fedhealthit.com/2020/04/hhs-covid-protect-now-data-initiative-taps-palantir-technologies/.

- As of May 29, 2020, the FDA has worked with more than 400 test developers and have issued 114 tests under EUAs, which include 101 molecular tests, 12 antibody tests, and 1 antigen test. [113]

- A second wave of COVID-19 cases could occur at the same time as influenza season in the fall. The development of combined diagnostic testing kits for both COVID-19 and influenza would allow providers to quickly determine whether a patient is infected with influenza or COVID-19. The kit would include assays for both COVID-19 and influenza. In particular, by providing point-of-care testing at hospitals for symptomatic cases, COVID-19 and influenza cases can be differentiated and separated to prevent co-infections and improve surveillance of the two viruses. CDC is working on a multiplex assay test combining COVID-19 and flu strains and is expected to make an EUA submission to the FDA.

    - On March 27, 2020, the FDA issued an EUA to Luminex for a COVID-19 laboratory diagnostic test—the NxTAG CoV Extended Panel Assay—which simultaneously detects 20 respiratory pathogens in a single test, including influenza A, A-H1, A-H3, and Influenza B and can run 96 samples at a time.[114]

    - On May 1, 2020, the FDA issued an EUA to BIOFIRE for a COVID-19 laboratory diagnostic test—the BioFire Respiratory Panel 2.1 (RP2.1)—which includes 22 respiratory pathogens in a single test, including COVID-19.[115] According to the company's press release, the test takes about 45 minutes and tests nasopharyngeal swab samples in transport media.[116]

- In the next generation of tests, researchers are using CRISPR gene-modification technology to recognize genetic signatures of the coronavirus that causes COVID-19 and then make cuts in the virus to release a fluorescent molecule to show whether the virus is present. The tests are self-contained, reducing the need for PPE and expensive lab equipment, and multiple samples can be run at once.[117]

- The FDA should continue to encourage development by the private sector of rapid, portable, point-of-care diagnostic tests, such as that recently developed by Abbott Laboratories, as well as high-throughput laboratory diagnostics.

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[113] U.S. Food and Drug Administration, *Emergency Use Authorizations*, *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd (last visited May 29, 2020).

[114] *Id.*

[115] Biomerieux, *BIOFIRE Respiratory Panel 2.1 (RP2.1) with SARS-CoV-2 obtains FDA Emergency Use Authorization* (May 4, 2020), *available at* https://www.biomerieux.com/en/biofirer-respiratory-panel-21-rp21-sars-cov-2-obtains-fda-emergency-use-authorization.

[116] *Id.*

[117] J. Palca, *CRISPR And Spit Might Be Keys To Faster, Cheaper, Easier Tests For The Coronavirus*, NPR (Apr. 17, 2020), *available at* https://www.npr.org/sections/health-shots/2020/04/17/835958797/crispr-and-spit-might-be-keys-to-faster-cheaper-easier-tests-for-the-coronavirus.

- The FDA should continue to encourage development by the private sector of other innovative new diagnostic tests and new methods of testing, especially tests and methods that potentially will reduce the demand for scarce testing resources and supplies given potential supply chain issues.

    - Saliva testing for COVID-19 could help minimize any shortage of swabs for sampling and increase testing of patients.[118] On April 10, 2020, the FDA issued an EUA to Rutgers Clinical Genomics Laboratory-Rutgers University for a COVID-19 high complexity molecular-based laboratory developed test that uses saliva as the primary test biomaterial, or sample, for the COVID-19 virus.[119]

    - Testing pooled samples for COVID-19 could allow for more individuals to be screened in a more efficient manner and help conserve scarce testing resources, including reagents for the COVID-19 assay.[120] Pooled testing works by taking samples from multiple individuals and combining them into a common pool and testing each pool, while also storing part of each sample individually in case additional testing is necessary. If the pool tests negative, all individuals whose samples are including in the pool are diagnosed as negative. If the pool tests positive, individual retesting of each sample that was stored individually is required to identify the positive individuals.[121]

    - An antigen test can identify virus in nose and throat secretions by looking for proteins on the surface of the virus, rather than genetic material that is inside the virus like a diagnostic test would.[122] This type of test can identify people who are currently infected with the virus and is similar to the technology used in a physician's office for a rapid strep test or a rapid flu test.

        - On May 8, 2020, Quidel announced that the company had received an EUA from the FDA to market a rapid antigen

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[118] Rutgers University, *New Rutgers Saliva Test for Coronavirus Gets FDA Approval* (Apr. 13, 2020), *available at* https://support.rutgers.edu/news-stories/new-rutgers-saliva-test-for-coronavirus-gets-fda-approval/.
[119] *Id.*; U.S. Food and Drug Administration, *Emergency Use Authorizations* (May 6, 2020), *available at* https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.
[120] Baha Abdalhamid, MD, PhD, et al., *Assessment of Specimen Pooling to Conserve SARS CoV-2 Testing Resources*, AMERICAN JOURNAL OF CLINICAL PATHOLOGY (Apr. 18, 2020), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7188150/.
[121] *See* New Jersey COVID-19 Information Hub, *What does pooled testing mean?* (Apr. 22, 2020), *available at* https://covid19.nj.gov/faqs/coronavirus-information/symptoms-tests-and-treatment/what-does-pooled-testing-mean.
[122] Richard Harris, *How Reliable Are COVID-19 Tests? Depends Which One You Mean,* NPR (May 1, 2020), *available at* https://www.npr.org/sections/health-shots/2020/05/01/847368012/how-reliable-are-covid-19-tests-depends-which-one-you-mean.

COVID-19 diagnostic assay.[123] The company has already placed about 36,000 test-analyzer instruments across the country, and it expects to increase manufacturing from 200,000 tests per week (week of May 11, 2020) to more than a million a week within several weeks.[124]

I. How can an adequate capacity for diagnostic testing be assured in time for a second wave?

- While states have formulated testing strategies for the near term, states, in connection with the federal government, should also determine whether an increased level of testing may be needed in the fall and, if so, begin to plan to meet the needed capacity.
    - This planning should include determining whether, and if so, where, excess laboratory capacity currently exists within a state that could be used for COVID-19 testing.
    - For example, academic laboratories certified to perform COVID-19 tests could be used more fully. Academic laboratories from universities including the Broad Institute of MIT and Harvard, the University of California, San Diego, Boston University, and others, report that hospitals have not utilized their laboratory services for reasons such as incompatible electronic health record software platforms or strict administrative procedures that are too prohibitive for establishing accounts with laboratories.[125] Many of these laboratories are able to manufacture reagents and do not experience the reagent supply chain bottlenecks as other laboratories.
- Congress has also provided funding that should significantly increase diagnostic testing capacity for a second wave.
- The Paycheck Protection Program and Health Care Enhancement Act (PPPHCEA) signed into law April 24, 2020, provided significant funding and requirements for planning and reporting for testing.
    - Specific to testing, PPPHCEA provides $25 billion for the U.S. Department of Health and Human Services (HHS) Public Health and Social Services Emergency Fund for necessary expenses to research, develop, validate, manufacture, purchase, administer, and expand capacity

[123] Quidel, *Quidel Receives Emergency Authorization for Rapid Antigen COVID-19 Diagnostic Assay* (May 8, 2020), *available at* https://ir.quidel.com/news/news-release-details/2020/Quidel-Receives-Emergency-Authorization-for-Rapid-Antigen-COVID-19-Diagnostic-Assay/default.aspx.
[124] Thomas M. Burton, *FDA Grants Emergency-Use Status for First Coronavirus Antigen Test*, THE WALL STREET JOURNAL (May 9, 2020), *available at* https://www.wsj.com/articles/fda-to-grant-emergency-use-status-for-first-coronavirus-antigen-test-by-quidel-corp-11589031815.
[125] *Id.*

for COVID-19 tests, some of which was specifically allocated.[126] Of the $25 billion, the Act provided:

- Not less than $11 billion to states, localities, territories, and tribes to develop, purchase, administer, process, and analyze COVID-19 tests, scale-up laboratory capacity, trace contacts, and support employer testing, and required states and territories receiving funding to submit to the Secretary of HHS, its plan for COVID-19 testing, including goals for the remainder of calendar year 2020.[127] The state testing plans are required to be submitted no later than 30 days after April 24, 2020, when the Act became law.[128]

    a. Not less than $2 billion of the $11 billion shall be allocated to the states, localities, and territories according to the formula that applied to the Public Health Emergency Preparedness cooperative agreement in fiscal year 2019.[129]

    b. Not less than $4.5 billion of the $11 billion shall be allocated to states, localities, and territories according to a formula methodology that is based on relative number of cases of COVID-19.[130]

    c. Not less than $750 million of the $11 billion shall be allocated in coordination with the Director of the Indian Health Services (IHS), to tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes.[131]

- Not less than $1.8 billion to NIH to partner with government and non-government entities to develop, validate, improve, and implement testing technologies, and accelerate point-of-care and rapid testing research and development.[132]

- Not less than $1 billion to the CDC for surveillance, epidemiology, laboratory capacity expansion, contact tracing, public health data surveillance and analytics infrastructure modernization.[133]

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126 Paycheck Protection Program and Health Care Enhancement Act, Pub. L. 116-139 (2020).
127 *Id.*
128 *Id.*
129 *Id.*
130 *Id.*
131 *Id.*
132 *Id.*
133 *Id.*

- Not less than $1 billion to BARDA for advanced research, development, manufacturing, production, and purchase of COVID-19 tests and supplies.[134]

- $600 million to the Health Resources and Services Administration (HRSA) for grants under the Health Centers program and for grants to federally qualified health centers.[135]

- $225 million to rural health clinics through grants and other mechanisms for COVID-19 testing and related expenses.[136]

- $22 million to FDA to support activities associated with tests and related administrative activities.[137]

- Up to $1 billion was provided to cover costs for testing uninsured individuals.[138]

  - The remaining money that is not specifically allocated can be used by HHS in accordance with the provisions in this section.

- The PPPHCEA requires HHS to submit several reports related to COVID-19 testing to Congress.

  - Within 21 days, HHS must report on the status of COVID-19 testing to include data on demographic characteristics including race, ethnicity, age, gender and geographic region; and the number and rates of COVID-19 cases, hospitalizations and deaths.[139] The "Paycheck Protection and Health Care Enhancement Act Disaggregated Data on U.S. Coronavirus Disease 2019 (COVID-19) Testing" report was submitted May 15, 2020.[140]

  - Within 30 days, HHS must submit a COVID-19 strategic testing plan to assist states, localities, territories, and tribal organizations.[141] The

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[134] *Id.*
[135] *Id.*
[136] *Id.*
[137] *Id.*
[138] *Id.*
[139] *Id.*
[140] U.S. Department of Health and Human Services and Centers for Disease Control and Prevention, *Report to Congress on Paycheck Protection Program and Health Care Enhancement Act Disaggregated Data on U.S. Coronavirus Disease 2019 (COVID-19) Testing* (May 15, 2020), *available at* https://www.help.senate.gov/imo/media/doc/FY%202020%20CDC%20RTC%20on%20COVID-19%20Testing%20Data%20-%20CDCfinalclean.pdf.
[141] Paycheck Protection Program and Health Care Enhancement Act, Pub. L. 116-139 (2020).

"COVID-19 Strategic Testing Plan" report was submitted on May 24, 2020.[142]

- Within 180 days, HHS must report on the number of positive COVID-19 diagnoses, hospitalizations and deaths, with detailed data to include an epidemiological analysis.[143]

- In addition, many state governors have formed COVID-19 testing task forces to evaluate their diagnostic testing capacity needs, create testing metrics, increase testing capacity, and track testing data.

- To ensure the states meet their testing goals, the Federal government procured FDA-authorized swabs and transport media, and is distributing those supplies to a single location in each state determined by the governor's office.[144] For May, the Federal government will distribute 12.9 million swabs and 9.8 million tubes of transport media to the states.[145]

- To ensure that the states have the collection supplies that they need through December 2020, the Federal government plans to acquire 100 million swabs and 100 million tubes of viral transport media, and distribute these supplies to the states as requested to meet their individual state plans.[146]

- Congress and the Executive Branch should work with the states to ensure the funding provided by the PPPHCEA is being invested to increase capacity for diagnostic testing.

J. <u>What changes need to be made to have a more unified testing capacity in the U.S.?</u>

- There have been significant obstacles to date in creating a unified and robust testing capacity in the U.S., including access to necessary supplies and fully utilizing all available testing capacity.

- In the current outbreak, private companies and private laboratories not only developed numerous diagnostic tests, including rapid diagnostics, but they also provided the vast majority of testing capacity for patient samples in the U.S.

- In the federal government, CDC, FDA, and CMS each have a role in overseeing the PHL network and the private laboratory network. FDA regulates the test itself, while CMS oversees the performance of the laboratory. CDC provides subject

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142 U.S. Department of Health and Human Services, Report to Congress, COVID-19 Strategic Testing Plan (May 24, 2020).
143 Paycheck Protection Program and Health Care Enhancement Act, Pub. L. 116-139 (2020).
144 U.S. Department of Health and Human Services, Report to Congress, COVID-19 Strategic Testing Plan 20 (May 24, 2020).
145 *Id.*
146 *Id.*

matter expertise and guidance to the labs. Congress and the Executive Branch should study how to more clearly define the roles and responsibilities for overseeing diagnostic tests.

- Efforts should be made to ensure that, if the private sector will ultimately be called upon to provide diagnostic testing development and capacity, that it is fully engaged at an earlier point in the process when a new infectious disease emerges. The inclusion of the private sector in the testing response has established an important precedent for future outbreaks and continues to be needed for the response to a possible second wave.

- The Executive Branch should continue to work with states to ensure that states can obtain adequate supplies for testing, that all available diagnostic testing capacity is utilized, and that states create and implement effective testing strategies.

- Congress and the Executive Branch should evaluate the efforts made by the FDA to streamline the EUA process and make any additional changes that are needed before a potential increase in COVID-19 cases in the fall.

- At an appropriate time, Congress and the Executive Branch should study the development of COVID-19 diagnostic tests by the CDC, including issues related to the development and deployment of the test, to determine whether changes should be made going forward.

K. How much contact tracing is needed to support an adequate level of testing?

- Contact tracing is the process of tracing and monitoring the contacts of an individual who has been identified as being infected with a virus.[147] Contact tracing is an important element of a comprehensive testing strategy to help contain COVID-19 and prevent additional transmission.

- Congress has provided additional support to states and localities to ensure adequate contact tracing.

    - On April 23, 2020, the CDC awarded $631 million to states and localities through the CARES Act to enhance COVID-19 testing, contact tracing, and containment efforts.[148] CDC has completed the distribution of those funds.[149]

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[147] Centers for Disease Control and Prevention, *Contact Tracing* (Apr. 30, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/php/open-america/contact-tracing.html.
[148] U.S. Department of Health and Human Services, *HHS Announces CARES Act Funding Distribution to States and Localities in Support of COVID-19 Response* (Apr. 23, 2020), *available at* https://www.hhs.gov/about/news/2020/04/23/hhs-announces-cares-act-funding-distribution-to-states-and-localities-in-support-of-covid-19-response.html.
[149] Centers for Disease Control and Prevention, *CDC Coronavirus Funding to Jurisdictions* (Apr. 23, 2020) *available at* https://www.hhs.gov/about/news/2020/04/23/updated-cdc-funding-information.html.

- On Friday April 24, 2020, President Trump signed the Paycheck Protection Program and Health Care Enhancement Act into law.[150] As previously discussed, the law provides an additional $25 billion to the Public Health and Social Services Emergency Fund for necessary expenses to research, develop, validate, manufacture, purchase, administer, and expand capacity for COVID-19 tests to effectively monitor and suppress COVID-19, including, among other things, to conduct surveillance and contact tracing.[151]

- The Executive Branch has issued guidelines and principles to help guide state, local, and tribal governments develop contact tracing programs. These documents highlight the important role of contact tracing to stop chains of transmission.

  - "The Guidelines for Opening Up America Again" issued by the White House and the CDC emphasize the need for contact tracing for contacts of individuals infected with COVID-19 and identify contact tracing as a core state preparedness responsibility.[152]

  - The CDC has issued "Principles of Contact Tracing" that provide basic principles of contact tracing to stop COVID-19 transmission.[153] The CDC also has issued a "Sample Training Plan" for state and local public health jurisdictions to consider when developing their own plan for contact tracers.[154]

  - The director of the CDC, Dr. Robert Redfield, recently outlined the Agency's contact tracing strategy that includes enhancing the public health workforce in states to enable adequate contact tracing.[155] As of April 21, 2020, the CDC had 600 disease experts deployed across the country, had sent community protection teams to nine states, and had CDC teams deployed in four other states to help contact tracing efforts, among other things.[156] In addition, the CDC is providing the CDC Foundation with $45 million to hire an additional 650 workers at state health departments.[157]

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150 Paycheck Protection Program and Health Care Enhancement Act, Pub. L. 116-139 (2020).
151 *Id.*
152 White House, *Guidelines: Opening Up America Again* (Apr. 2020), *available at* https://www.whitehouse.gov/openingamerica/.
153 Centers for Disease Control and Prevention, *Principles of Contact Tracing* (Apr. 29, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/php/principles-contact-tracing.html.
154 Centers for Disease Control and Prevention, *Contact Tracing Training*, *available at* https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/index.html (last visited on May 8, 2020).
155 Rob Stein and Selena Simmons-Duffin, *CDC Director Shares Plan on Contact Tracing*, NPR (Apr. 21, 2020), *available at* https://www.npr.org/2020/04/21/840522572/cdc-director-shares-plan-on-contact-tracing.
156 *Id.*
157 *Id.*

- There is significant variation in state efforts to develop contact tracing programs. While each state's needs will be different, states, in partnership with the federal government, should asses the level of contact tracers needed to support these efforts and how to meet those needs.

    - There is significant variation in state planning for contact tracing. Some states are engaging in broad efforts to promote contact tracing. For example, Massachusetts is spending $44 million on its contact tracing program and has hired a thousand people.[158] Similarly, Maryland expects to hire 1,000 workers to perform contact tracing, and Michigan has already trained 2,200 volunteers to do contact tracing.[159]

    - Alternatively, other states have adopted narrower strategies for contact tracing. For example, Mississippi is hiring 20 additional staff for contact tracing and Utah has reassigned 30 workers from the Medicaid program for contact tracing.[160] Some states, like Iowa, are reassigning state workers to work as pandemic investigators, and help local health agencies conduct contact tracing.[161]

- According to the CDC, the "adoption and evaluation of digital tools may expand reach and efficacy of contact tracers."[162] The Surveillance System section of this outline includes additional initiatives for contact tracing, including technology that is being developed to assist with contact tracing.

L. <u>Preparation for seasonal influenza should be considered part of the overall COVID-19 response for the fall.</u>

- Public health leaders such as CDC Director Robert Redfield have noted a second wave of COVID-19 cases could occur at the same time as the U.S. seasonal influenza season, and further complicate the COVID-19 pandemic response effort.

- It should be a priority to differentiate COVID-19 cases from influenza cases, in order to rapidly detect outbreaks and prevent co-infections. Combined diagnostic testing kits for both COVID-19 and influenza should be ramped up and made available for the fall.

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158 O. Kay Henderson, *Iowa DHS workers to be dispatched for COVID contact tracing*, RADIO IOWA (Apr. 16, 2020), *available at* https://www.radioiowa.com/2020/04/16/iowa-dhs-workers-to-be-dispatched-for-covid-contact-tracing/.

159 Rob Stein and Selena Simmons-Duffin, *CDC Director Shares Plan on Contact Tracing*, NPR (Apr. 21, 2020), *available at* https://www.npr.org/2020/04/21/840522572/cdc-director-shares-plan-on-contact-tracing.

160 *Id.*

161 O. Kay Henderson, *Iowa DHS workers to be dispatched for COVID contact tracing*, RADIO IOWA (Apr. 16, 2020), *available at* https://www.radioiowa.com/2020/04/16/iowa-dhs-workers-to-be-dispatched-for-covid-contact-tracing/.

162 Centers for Disease Control and Prevention, *Contact Tracing* (Apr. 30, 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/php/open-america/contact-tracing.html.

- To the extent the response to seasonal influenza can be strengthened, this will lessen the potential added burden of influenza on the healthcare system while responding to COVID-19. Public health experts have stressed the importance of high influenza vaccination rates in the upcoming influenza season. Additional resources may be necessary to help public service messaging and promotion to increase influenza vaccination rates, which nationally are only about 45 percent.

    - Persons 65 years or older are a particularly vulnerable population to both seasonal influenza and COVID-19. On average, persons 65 years or older represent about 90 percent of deaths in a severe seasonal influenza season in the U.S. Special measures should be taken by the CDC and public health departments to promote and highlight vaccines indicated for seniors that boost the immune response. There is an FDA-approved high-dose influenza vaccine and an FDA-approved adjuvanted influenza vaccine for seniors that have been on the market for several years and have substantial evidence of superior efficacy over standard dose influenza vaccines.

    - Because seasonal influenza preparedness is intertwined with the fall response to COVID-19, steps should be taken to strengthen the supply chain of the U.S. influenza vaccine supply. Only about 53 percent of the U.S. seasonal influenza vaccines are produced in the U.S, with 47 percent of vaccines imported. The supply chain for influenza vaccines is globalized. Policies should be examined to encourage more U.S.-based production and supply for U.S. influenza vaccines.

M. Oversight of the funds appropriated by Congress for testing.

- The Executive Branch has acted swiftly to implement and use the funding and additional authorities provided by Congress for diagnostic and antibody testing in recent law. Among other examples:

    - On April 6, 2020, HHS announced that the CDC would provide $186 million in funding to state and local jurisdictions to support the COVID-19 response and augment core public health capabilities. Some of the public health capabilities include: (1) surveillance and predictive analytics; (2) laboratory capacity; (3) qualified frontline deployers; and (4) the ability to rapidly respond to emerging disease clusters in communities that had person-to-person spread of the virus.[163] The award was intended to support a range of activities such as lab equipment, supplies, staffing, shipping, infection control, surge staffing, monitoring of individuals, data management, and to supplement an existing cooperative agreement to state

[163] This was a supplemental award to the $25 million and $10 million initial awards announced Mar. 4, 2020, *available at* https://www.hhs.gov/about/news/2020/03/04/hhs-announces-initial-funding-jurisdictions-supporting-covid-19-response.html, and the $560 million award announced Mar. 11, 2020, which was distributed to the states by the CDC to assist them in COVID readiness, *available* at https://www.hhs.gov/about/news/2020/03/11/cdc-to-award-over-560-million-to-state-local-jurisdictions-in-support-of-covid-19-response.html.

jurisdictions through the Emerging Infections Program to enhance surveillance capabilities.[164]

- On April 8, 2020, HHS' Office of the Assistant Secretary for Health issued new guidance under the Public Readiness and Emergency Preparedness Act authorizing licensed pharmacists to order and administer COVID-19 tests that the FDA has authorized, effectively expanding patient access to testing for patients.[165]

- HHS announced on April 23, 2020, that CDC would use funds from the CARES Act to award $631 million to 64 jurisdictions through the existing "Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases" cooperative agreement to, among other things, expand capacity for testing, contact tracing, and containment. CDC has completed the distribution of those funds.[166]

- The CDC received $500 million from the CARES Act to modernize the public health infrastructure system at the CDC and state and local health departments to build a public health surveillance system that provides an automatic and interoperable data exchange in real-time, enabling a coordinated and timely response across the health system.[167]

- On April 29, 2020, NIH announced the Rapid Acceleration of Diagnostics (RADx) initiative—also referred to as a "Shark Tank"-like effort—aimed at speeding innovations, development, and commercialization of COVID-19 testing technologies, supported with $1.5 billion in federal funding. As part of the initiative, all inventors with rapid point-of-care or at-home technologies will compete in a national testing challenge, and finalists will be matched with technical, business, and manufacturing experts to increase their odds at success. The goal is to make millions of accurate and easy-to-use tests per week available to all Americans by the end of summer 2020.[168]

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[164] U.S. Department of Health and Human Services, *HHS Announces Upcoming Funding Action to Provide $186 Million for COVID-19 Response* (Apr. 6, 2020), *available at* https://www.hhs.gov/about/news/2020/04/06/hhs-announces-upcoming-funding-action-provide-186-million-covid19-response.html.

[165] U.S. Department of Health and Human Services, *HHS Statements on Authorizing Licensed Pharmacists to Order and Administer COVID-19 Tests* (Apr. 8, 2020), *available at* https://www.hhs.gov/about/news/2020/04/08/hhs-statements-on-authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.html.

[166] Centers for Disease Control and Prevention, *HHS Announces CARES Act Funding Distribution to States and Localities in Support of COVID-19 Response* (Apr. 23, 2020), *available at* https://www.cdc.gov/media/releases/2020/p0423-CARES-act.html.

[167] Healthcare Information and Management Systems Society, Inc., *CARES Act Provisions for Healthcare and Health IT* (Mar. 31, 2020), *available at* https://www.himss.org/news/cares-act-provisions-healthcare-and-health-it.

[168] National Institutes of Health, *NIH mobilizes national innovation initiative for COVID-19 diagnostics* (Apr. 29, 2020), *available at* https://www.nih.gov/news-events/news-releases/nih-mobilizes-national-innovation-initiative-covid-19-diagnostics.

- In April 2020, Health Resources and Services Administration (HRSA) funded community health centers received $1.3 billion for COVID-19 diagnostic testing.[169] The centers received nearly $583 million in additional funding for testing May 7, 2020.[170] The health centers report that 90 percent of the 1,385 centers are providing COVID-19 tests. In 16 states and Washington, D.C., all centers are providing tests. As of May 8, health centers provided 127,816 tests with 36,155 testing positive, (28 percent), which is double the national positive rate of 13 percent during the similar period.[171] More than 65 percent of the health centers offer walk-up and drive-thru testing and nearly 88 percent report that they are testing patients.

- Congress and the Executive Branch should continue to monitor the implementation and use of the large amounts of funding and authorities for diagnostic and antibody testing provided in recent legislation and assess if additional resources and authorities are necessary.

N. Oversight into whether the federal government should make additional investments to further increase the volume of testing.

- Congress should conduct oversight into whether the federal government should make additional investments to further increase the volume of testing. The question of additional investments should be examined while considering national testing and surveillance capacity, coupled with other possible investments that may produce higher or complimentary benefits.

    - For example, should Congress consider the idea of mobilizing an industry effort to make a better face mask for persons not on the medical frontlines?

    - Similarly, should Congress require a larger public communication effort to promote personal responsibility as part of a layered approach to combating COVID-19?

O. Areas of testing that merit further research.

- Some questions for further examination include: (1) How will we establish which, if any, tests for an antibody response correlate with immunity? (2) How do specific

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169 U.S. Department of Health and Human Services, *HHS Awards $1.3 billion to Health Centers in Historic U.S. Response to COVID-19* (Apr. 8, 2020), *available at* https://www.hhs.gov/about/news/2020/04/08/hhs-awards-billion-to-health-centers-in-historic-covid19-response.html.

170 U.S. Department of Health and Human Services, *HHS Awards $1.3 billion to Health Centers in Historic U.S. Response to COVID-19* (Apr. 8, 2020), *available at* https://www.hhs.gov/about/news/2020/04/08/hhs-awards-billion-to-health-centers-in-historic-covid19-response.html.

171 Bradley Corallo and Jennifer Tolbert, *Impact of Coronavirus on Community Health Centers,* Kaiser Family F (May 20, 2020), *available at* https://www.kff.org/coronavirus-covid-19/issue-brief/impact-of-coronavirus-on-community-health-centers/.

real-time PCR testing strategies affect the risk of transmission in certain circumstances? For example, is it more effective to test athletes before a game or to test employees who work in certain environments at the start of a work shift or other regular interval rather than to largely wait until a person develops symptoms to test? (3) How can we improve our understanding of the meaning of test results? (4) Given their scalability, could serological tests under development be used for diagnostic testing for active infection?

- A combination of viral and serology (antibody) testing may increase the ability to diagnose patients with mild symptoms or identify patients at higher risk of severe disease.[172] This should be further researched by scientists in industry, academia, and government.

- HHS's strategic testing plan identified several promising emerging technologies that should be further studied, including Next-generation Sequencing (NGS), Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), and adjunctive technologies.[173]

II. Surveillance

A. What are the current U.S. surveillance systems and capacity for COVID-19?

- The U.S. does not currently have a unified, comprehensive, and designated national surveillance system specific to COVID-19. Instead, CDC is using multiple surveillance systems run in collaboration with state, local, and territorial health departments, public health, commercial and clinical laboratories, vital statistics offices, health care providers, emergency departments, and academic partners to monitor COVID-19 in the U.S.[174] CDC's surveillance program for COVID-19 "is built on a combination of existing influenza and viral respiratory diseases surveillance systems, syndromic surveillance systems, case reporting systems, proactive monitoring for asymptomatic cases in areas of demonstrated vulnerabilities, commercial laboratory reporting, ongoing research platforms employed for the COVID-19 response, and new systems."[175]

    - According to the CDC, the U.S. COVID-19 surveillance goals are to (1) monitor the spread and intensity of COVID-19 disease in the U.S.; (2)

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[172] J. Zhao, et al, *Antibody Responses to SARS-CoV-2 in Patients of Novel Coronavirus Disease 2019*, THE LANCET, SSRN (Mar. 3, 2020), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3546052#.
[173] U.S. Department of Health and Human Services, Report to Congress, COVID-19 Strategic Testing Plan 31-32 (May 24, 2020).
[174] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), COVIDView, Purpose and Method*, *available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/purpose-methods.html (last updated Apr. 17, 2020).
[175] Centers for Disease Control and Prevention, CDC Activities and Initiatives Supporting the COVID-19 Response and the President's Plan for Opening America Up again (May 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/CDC-Activities-Initiatives-for-COVID-19-Response.pdf.

understand disease severity and the spectrum of illness; (3) understand risk factors for severe disease and transmission; (4) monitor for changes in the virus that causes COVID-19; (5) estimate disease burden; and (6) produce data for forecasting COVID-19 spread and impact.[176]

- According to the CDC, the "key systems are case-based reporting through the National Notifiable Diseases Surveillance System (NNDSS), laboratory-based surveillance, syndromic-surveillance data reported through the National Syndromic Surveillance Program (NSSP), and data on healthcare system capacity reported through the [National Healthcare Safety Network] NHSN."[177] Additional systems such as COVID-Net provide publicly available information for meeting secondary objectives.[178]
    - The CDC uses multiple systems and epidemiology networks which "use laboratory submitted specimens, electronically transmitted data, and other sources to generate an ongoing picture of disease spread, intensity, and severity, and produce data to address the key questions for directing and refining the US response."[179] In addition to the NNDSS, NSSP, and NHSN these platforms include: COVID-19 case-based surveillance; PHLs; National Respiratory and Enteric Virus Surveillance System (NREVSS); commercial labs; U.S. Outpatient Influenza like illness Surveillance Network (ILINet); laboratory-confirmed outpatient (OP) surveillance; U.S. Flu Vaccine Effectiveness (VE) network (acute respiratory illness); New Vaccine Surveillance Network (NVSN) – pediatrics; CDC/DVD SPHERES; FluSurvnet – all ages; Hospitalized Adult Influenza Vaccine Effectiveness Network (HAIVEN); Influenza ICU Vaccine Effectiveness Study; Pediatric Intensive Care Influenza Network (PICFLU); special research studies; serologic surveys; modeling based on epidemiological inputs; modeling work with broad a coalition of modelers led by CDC; field studies; Flu Transmission Evaluation Study (FLuTES); Household Influenza Vaccine Effectiveness Study (HIVES); and pandemic cohorts (community, households, health care workers, pregnant women, long-term care facilities).[180]

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176 Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), COVIDView, Purpose and Method, available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/purpose-methods.html (last updated Apr. 17, 2020).

177 Centers for Disease Control and Prevention, CDC Activities and Initiatives Supporting the COVID-19 Response and the President's Plan for Opening America Up again (May 2020), *available at* https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/CDC-Activities-Initiatives-for-COVID-19-Response.pdf.

178 *Id.*

179 *Id.*

180 *Id.*

- The NNDSS "helps monitor, control, and prevent about 120 diseases."[181] About 3,000 public health departments gather data on these diseases from health care providers, laboratories, hospitals, and other partners and those health departments and the CDC use the data to monitor, control and prevent the occurrence and spread of the diseases it monitors.[182] The CDC's Division of Health Informatics and Surveillance (DHIS) supports the NNDSS "by receiving, securing processing, and providing nationally notifiable disease data to disease-specific CDC programs."[183] In addition DHIS supports local, state, and territorial public health departments in helping them collect, manage, and submit data to CDC for the NNDSS.[184] A list of the 2020 National Notifiable Conditions, which includes COVID-19, is available on CDC's website.[185]

- CDC launched a new website—COVIDView—which contains surveillance data that brings together influenza like illnesses with syndromic management databases to be able to track respiratory disease across the U.S. COVIDView provides a weekly surveillance summary of U.S. COVID-19 activity and an interpretation of key indicators that have been adapted to track the COVID-19 pandemic in the U.S.

- The Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET) is a population-based surveillance system that collects data on laboratory-confirmed COVID-19-associated hospitalizations through a network of over 250 acute-care hospitals in 99 counties in 14 states who are participating in the Emerging Infections Program and the Influenza Hospitalization Surveillance Project.[186] In addition to data on hospitalization rates associated with COVID-19, COVID-NET provides clinical information on COVID-19 hospital patients, including age, sex, race/ethnicity, and underlying health conditions.

- The SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES) is a genomics consortium to coordinate sequencing of the virus that causes COVID-19 throughout the U.S.[187] SPHERES is led by CDC's Advanced Molecular Detection (AMD) program, which is a program that helps "modernize the public health system's disease-investigation capabilities by employing the latest technologies and improving AMD capacity throughout the

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[181] Centers for Disease Control and Prevention, *National Notifiable Diseases Surveillance System (NNDSS), available at* https://wwwn.cdc.gov/nndss/.
[182] *Id.*
[183] *Id.*
[184] *Id.*
[185] Centers for Disease Control and Prevention, *2020 National Notifiable Conditions*, *available at* https://wwwn.cdc.gov/nndss/conditions/notifiable/2020/.
[186] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Hospitalization Surveillance Network COVID-NET*, *available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html (last updated May 1, 2020).
[187] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), SPHERES, SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance*, *available at* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/spheres.html (last accessed on May 8, 2020).

nation."[188] Over the past six years AMD has "invested in federal, state, and local public health laboratories to expand the use of pathogen genomics and other advanced laboratory technologies to strengthen infectious disease surveillance and outbreak response."[189] According to the CDC, with extensive participation from clinical labs and PHLs, academic institutions, and the private sector, "the SPHERES consortium aims to generate information about the virus that will strengthen COVID-19 mitigation strategies."[190]

- CDC's surveillance strategy also includes serology testing to better understand how many infections of COVID-19 have occurred at different points in time; in different locations; and within different populations in the U.S.[191] CDC is working with public and private partners on a variety of seroprevalence surveys to provide a better estimate of the incidence of infection and to help inform control measures. The types of seroprevalence surveys CDC is conducting include large-scale geographic, community-level, and special populations.

- These and other CDC surveillance systems continue to be under review by the Committee.

B. Are the current surveillance systems and capacity sufficient?

- It is unclear how effective the existing surveillance networks will be in terms of detecting signals of COVID-19.

    - A "Morbidity and Mortality Weekly Report" released by CDC on May 1, 2020, examined the various factors that contributed to the accelerated spread of COVID-19 between February and March 2020. The report noted that "[u]nrecognized transmission played a key role in the initiation and acceleration phases of the U.S. outbreak. Cases were not detected during this time for various reasons. First, introduction of the virus into the United States occurred during the annual influenza season. Although syndromic surveillance systems tracked respiratory illness in outpatient settings and emergency departments in many U.S. jurisdictions, including areas where early COVID-19 clusters were detected, such as Seattle, Washington, none of these systems detected unusual trends during the early part of the acceleration period because of the preponderance of

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[188] Centers for Disease Control and Prevention, *Advanced Molecular Detection (AMD), available at* https://www.cdc.gov/amd/; Centers for Disease Control and Prevention, *Advanced Molecular Detection (AMD), Who We Are, available at* https://www.cdc.gov/amd/who-we-are/index.html.

[189] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), SPHERES, SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance, available at* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/spheres.html (last accessed on May 8, 2020).

[190] *Id*.

[191] Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19), *Serology Surveillance Strategy, available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/serology-surveillance/index.html (last updated on Apr. 28, 2020).

seasonal influenza illness."[192] While we still do not know whether COVID-19 is seasonal, this is troubling for the fall when influenza season will begin again.

- Other tools that are being rolled out, such as COVIDView and a potential app for case reporting, are in the early stages, and it is currently unclear how comprehensive the data collected from those tools will be.

    - While the data gathered by COVID-NET is critical surveillance information which will also allow experts to learn more about the virus, there are limitations to the data.

    - For example, according to information posted on COVIDView, two indicators from existing surveillance systems—ILINet and the NSSP—are being used to track outpatient or emergency department visits for illness with symptoms compatible with COVID-19.[193] While these two systems are being leveraged, recent changes in health care-seeking behavior due to the pandemic are likely affecting data reported from ILINet and NSSP, making it difficult to draw further conclusions from the two systems at this time. According to CDC, tracking these systems moving forward will give additional insight into illness related to COVID-19. However, if health care-seeking behavior does not revert back to what it was pre-COVID-19, it is unclear whether these systems, and others, will be as effective as they were prior to COVID-19.

    - In addition, while COVID-NET includes 99 counties in 14 states covering 10 HHS regions, it only accounts for about 10 percent of the U.S. population.[194] While the surveillance area is similar to the U.S. population by demographics, information might not be generalizable to the entire country.

    - Finally, COVID-NET's website contains a pop-up disclaimer which notes that cases are identified by reviewing hospital, laboratory, and admission databases and infection control logs for patients who are hospitalized with a documented positive SARS-CoV-2 test. However, the disclaimer notes

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[192] Anne Schuchat, MD, *CDC COVID-19 Response Team, Centers for Disease Control and Prevention*, Morbidity and Mortality Weekly Report, *Public Health Response to the Initiation and Spread of Pandemic COVID-19 in the United States, February 24-April 21, 2020* (May 1, 2020), *available at* https://www.cdc.gov/mmwr/volumes/69/wr/mm6918e2.htm?s_cid=mm6918e2_w.

[193] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), COVIDView Weekly Summary, Key Updates for Week 17, ending April 25, 2020*, *available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcovid-data%2Fcovidview.html (last viewed on May 4, 2020).

[194] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Hospitalization Surveillance Network COVID-NET, available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html (last updated May 1, 2020).

that laboratory confirmation is dependent on clinician-ordered testing, therefore the rates provided may be underestimated as COVID-19-associated hospitalizations could be missed due to test availability and provider or facility practices.

- Additionally, there are reports that CDC plans to roll out an app, based on Fast Healthcare Interoperability Resources standards, that will accelerate the reporting of COVID-19 cases by making case reporting more automated.[195] The app will increase efficiency in case reporting for healthcare providers who are not able to automatically send case reports to public health agencies through their health IT systems.

- Asymptomatic and pre-symptomatic transmission also calls for surveillance broader than just individuals who show symptoms of COVID-19.
  - CDC has recently updated its priorities for COVID-19 to include certain persons without symptoms. However, it is unclear how much that level of asymptomatic testing will contribute to the overall U.S. surveillance system.

- Serology testing and seroprevalence surveys can help CDC determine how much of the population has been infected, how that changes over time, different characteristics or risk factors associated with SARS-CoV-2, how many people had mild symptoms or were asymptomatic, and how long antibodies can be found after infection. However, serology testing cannot determine how much of the population is immune to COVID-19 and cannot get infected again, how many antibodies are needed for someone to have immunity, how long someone will have immunity, whether someone can be re-infected, or if people with antibodies can return to work.

- CDC is expanding surveillance tracking to get a better understanding of how common certain clinical outcomes are, such as blood clots, but they do not currently have a full sense of the magnitude of certain clinical outcomes.

- The "Guidelines for Opening Up America Again" emphasize the need for contact tracing for contacts of those with COVID-19 positive results, and sentinel surveillance sites to help identify asymptomatic or mild cases in a community, particularly among populations more severely impacted by COVID-19, including older individuals, lower-income individuals, racial minorities, and Native Americans. However, as previously noted, the public health care workforce will need to be enhanced, both through appropriate training and expansion, for there to be sufficient contact tracing to support an adequate level of testing.

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[195] Heather Landi, *CDC plans to roll out app in May to speed up COVID-19 case reporting,* FIERCE HEALTHCARE (Apr. 17, 2020), *available at* https://www.fiercehealthcare.com/tech/cdc-plans-to-roll-out-reporting-app-for-covid-19-cases-may.

- Congress and the Executive Branch should define the intended purpose of a COVID-19 surveillance system (early alert/advanced warning system, forecasting supply needs, contact tracing, tracking cases, etc.) and determine what a comprehensive surveillance strategy should look like to achieve that purpose.

C. Should the current system be upgraded or enhanced? If so, in what ways?

- Surveillance systems are only as good as the amount, type, and quality of data you collect with them. The level of surveillance will also largely depend on the volume and type of testing that is conducted throughout the U.S. While the existing surveillance systems for influenza and the tools that have been developed to surveil COVID-19 are a good baseline infrastructure of systems that the U.S. should leverage, they need to be evaluated and enhanced to ensure quality data collection and surveillance for the purpose of COVID-19 surveillance.

- Legislation recently passed by Congress and enacted into law in response to COVID-19 provides further funding for states, CDC, and other entities that can be utilized for surveillance, and Congress should work to ensure that the laws are implemented as intended in advance of an increase in COVID-19 cases in the fall.

    - Congress has also previously provided funding to improve public health surveillance, including for a multi-year effort to support modernization of public health data surveillance and analytics. Congress and HHS ensure that the funds are appropriately used to improve surveillance.

- Legislation recently passed by Congress and enacted into law, as well as other actions taken by the Executive Branch, have also made improvements to data collection relevant to surveillance for COVID-19.

    - The CARES Act requires any laboratory that performs tests to detect the virus that causes COVID-19 to report the results, both positive and negative, to the Secretary of HHS during the period of the public health emergency.

    - In addition, CDC has posted information on its website regarding the reporting of COVID-19 laboratory data.[196] In addition to providing information on reporting laboratory data, the website states that "[t]he public health response to COVID-19 depends on comprehensive laboratory testing data. These data will contribute to understanding disease incidence and testing coverage and can contribute to the identification of supply chain issues for reagents and other material,"

[196] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Reporting COVID-19 Laboratory Data*, *available at* https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html (last visited on May 8, 2020).

further highlighting the importance of comprehensive data collection and surveillance.[197]

- Congress, the Executive Branch, and state health departments should work to ensure that these data collection requirements are being adhered to, and if they are not, work to close those gaps and variations in reporting. They should also examine whether additional requirements are needed to ensure adequate surveillance.

- To ensure appropriate tracking, response, and mitigation of COVID-19 in nursing homes, CMS announced new regulatory requirements which require nursing homes to report cases of COVID-19 directly to the CDC. CMS will also require nursing homes to fully cooperate with CDC surveillance efforts around COVID-19 spread. On May 8, 2020, CMS published an interim final rule on requirements for notification of confirmed and suspected COVID-19 cases among residents and staff in nursing homes. Nursing homes are now required to report COVID-19 data to the CDC beginning May 8, 2020. All 15,000 nursing homes will be reporting this data directly to the CDC through its reporting tool.[198]

- Through the NNDSS Modernization Initiative (NMI) CDC is working to enhance NNDSS' ability to provide more comprehensive, timely, and higher quality data for public health decision making.[199]

  - Congress should work with the Executive Branch to evaluate the anticipated timeline of these enhancements and whether they are adequate to meet CDC's COVID-19 surveillance goals.

- CDC updated its "Evaluation and Testing Guidance for COVID-19," revising priorities for testing patients with suspected COVID-19 infection on April 27, 2020, and then again on May 3, 2020.

  - Recently, CDC has made multiple changes to its "Evaluation and Testing Guidance for COVID-19."[200] Understanding there will be necessary changes when scientists and experts learn more about the virus and as the U.S. testing capacity increases, CDC should be clear when it makes such changes and why they are being made to ensure public awareness. This will also help healthcare professionals have a better understanding of the most up-to-date recommendations of who to prioritize for testing, assist

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197 *Id*.

198 Centers for Medicare and Medicaid Services, *Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes, Ref: QSO-20-29-NH* (May 6, 2020), *available at* https://www.cms.gov/files/document/qso-20-29-nh.pdf.

199 Centers for Disease Control and Prevention, *National Notifiable Diseases Surveillance System (NNDSS), available at* https://wwwn.cdc.gov/nndss/.

200 Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Evaluation and Testing, available at https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html* (last updated on Apr. 27, 2020).

with planning and preparedness, and allow for a more reliable surveillance system to be established.

- Once the new guidance takes effect, Congress, the Executive Branch, and the states should evaluate whether the level of asymptomatic testing being conducted is sufficient to meet CDC's surveillance goals for the U.S. of monitoring the spread and intensity of COVID-19 disease in the U.S., monitoring for changes in the virus that causes COVID-19, and producing data for forecasting COVID-19 spread and impact. If not, CDC should issue further guidance on the necessary level of asymptomatic testing to achieve these goals.

- Private companies and academia have announced initiatives, partnerships, and tools that will help serve as early warning systems and/or track the spread of COVID-19.

  - Apple and Google announced that they plan to launch a comprehensive solution that includes application programing interfaces and operating system-level technology to assist in enabling contact tracing. On May 20, 2020, Apple and Google announced that their Exposure Notifications technology, which is API that "enable[s] apps created by public health agencies to work more accurately, reliably and effectively across both Android and iPhones," is available to public health agencies on both iOS and Android.[201]

  - Facebook and Carnegie Mellon University have partnered to track and forecast the spread of COVID-19 utilizing voluntary surveys about an individual's symptoms.

  - Premier has been enhancing existing data and technology capabilities to surveil for COVID-19 symptoms and pinpoint hotspots, predict disease progression and surge, determine the supplies necessary to care for the infected population, improve the quality of medical interventions, and ultimately prevent the spread of the disease.

- Some laboratories have the ability to electronically report test results through their health IT system. In addition, some laboratories and/or others are researching the technology and ability to electronically report test results, allowing for real time surveillance.

  - With appropriate protections for patients, the private sector, states, and Executive Branch should explore the feasibility of diagnostic testing technology to automatically report results for purposes of disease monitoring, including at-home platforms. This would enhance

[201] Google, *Exposure Notification API launches to support public health agencies,* joint statement from Apple and Google (May 20, 2020), *available at* https://blog.google/inside-google/company-announcements/apple-google-exposure-notification-api-launches/.

surveillance efforts by assisting with more timely contact tracing, resource forecasting, and improving the overall public health response.

- In addition to reporting positive or negative cases, additional data is needed to better understand the virus, disparities, and how the virus affects different populations (age, race, ethnicity, occupation, etc.). For example, recent reports regarding racial and ethnic disparities highlight the importance of gathering additional details. CDC has started to collect this data; however, it is incomplete.
    - CDC recently updated the COVID-19 Case Report Form to standardize the reporting of information on COVID-19 cases.[202] The form collects key information on COVID-19 patients, including demographic, clinical, and epidemiologic characteristics; exposure and contact history; and course of clinical illness and care received.[203] Specific changes to the form include added probable case determination; added variables to better capture data on at-risk populations; added variables related to healthcare, workplace, and specific community exposures, such as correctional facilities or schools/childcare settings; added questions related to whether cases are associated with an outbreak, and if so, which outbreak specifically; expanded list of underlying medical conditions, including severe obesity, hypertension, and autoimmune disorders; expanded list of COVID-19 symptoms; removed questions related to exposure within China; removed questions related to respiratory diagnostic testing for other illnesses; and improved and streamlined collection of information related to specimen testing for COVID-19.[204]
        - Congress and the Executive Branch should consider whether these reporting requirements are adequate, and if not, whether additional reporting requirements are needed to ensure complete and actionable data.
- Other ideas are being explored and, if effective, should be considered to create a more comprehensive surveillance system.
    - For example, an idea being explored by researchers is sampling wastewater in wastewater systems to detect whether there is virus in a community since the virus gets secreted. The idea is to have a sentinel system that tests wastewater instead of people. New and innovative ideas like this one should be considered in the event that they could substantially contribute to a more robust surveillance system.

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[202] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Reporting a Confirmed Case, available at* https://www.cdc.gov/coronavirus/2019-ncov/php/reporting-pui.html.
[203] *Id.*
[204] Email from Centers for Disease Control and Prevention, to Capitol Hill staff, Capitol Hill Announcement, Updated CDC COVID-19 Case Report Form (May 11, 2020) (On file with Committee staff).

  - Another idea being explored to detect community transmission of COVID-19 is sample pooling. This method could result in more individuals being tested which would enhance surveillance, while at the same time preserving testing supplies.

- In preparation for a fall outbreak, Congress and the Executive Branch should continue to consider additional short-, medium-, and long-term solutions to the issue of surveillance. These solutions will be even more critical in the fall when influenza season begins again and there is an increase in influenza-like illnesses across the U.S.

- In the short- and medium-term, the capacity created by the private sector to conduct COVID-19 tests should be maintained and expanded.

  - This capacity, particularly with a rapid point-of-care test, could be repurposed to routine surveillance once the rate of COVID-19 cases have abated.

  - Serology tests may further be layered on to understand the seroprevalence and immunity levels—and thus the risk of a broader outbreak if cases do re-emerge—in a community.

  - Existing surveillance systems can also be used to ascertain each week the number of persons with a highly sensitive but nonspecific syndrome (for example, acute respiratory infection), and testing a subset of these persons for COVID-19. This approach was used during the 2009 influenza pandemic.

  - Existing surveillance systems should be evaluated to determine how accurate and comprehensive the data sets are to ensure that the surveillance systems are reliable and actionable for COVID-19. In addition, Congress and the Executive Branch should examine whether a unified and comprehensive national surveillance system dedicated to COVID-19 is needed.

- In the long-term, Congress should evaluate whether a sentinel surveillance system should be authorized and appropriated.

  - Former FDA Commissioner Scott Gottlieb has proposed creating such a system.

  - A sentinel surveillance system would collect high-quality data from specific locations and test a statistically representative sample of patients to detect where and when the virus may be spreading. Such a system could help find pockets of infection before they multiply into larger outbreaks.

  - The system would also require an efficient data collection system that allows cases to be identified and tracked in real time without overburdening providers with data entry and case reports.

- In addition to considering authorization and funding for a modernized surveillance network, Congress should also consider issues related to data accuracy and security, as well as privacy issues, particularly when patient health information is implicated.

III. Recommendations

A. Testing

1. Recommendations for Congress and the Executive Branch

- Once the current phase of the pandemic has subsided, it will be critical to restock and continue to increase the needed level of supplies for diagnostic testing in anticipation of an increase in COVID-19 cases in the fall.
  - Congress and the Executive Branch should also consider what diagnostic tests and testing supplies, and at what level, should be included in the Strategic National Stockpile. These supplies have not been previously included in the SNS.

- Congress, the Executive Branch, and the states should consider ways to encourage the submission or more standardized state testing data to the CDC.

- FDA should continue to encourage development by the private sector of rapid, portable, point-of-care diagnostic tests, as well as high-throughput laboratory diagnostics.

- FDA should continue to encourage development by the private sector of other innovative new diagnostic tests and new methods of testing, especially tests and methods that potentially will reduce the demand for scarce testing resources and supplies given potential supply chain issues.

- Congress and the Executive Branch should work with the states to ensure the funding provided by the PPPHCEA is being invested to increase capacity for diagnostic testing.

- In the federal government, CDC, FDA, and CMS each have a role in overseeing the PHL network and the private laboratory network. FDA regulates the test itself, while CMS oversees the performance of the laboratory. CDC provides subject matter expertise and guidance to the labs. Congress and the Executive Branch should study how to more clearly define the roles and responsibilities for overseeing diagnostic tests.

- The Executive Branch should continue to work with states to ensure that states can obtain adequate supplies for testing, that all available diagnostic testing capacity is utilized, and that states create and implement effective testing strategies.

- Congress and the Executive Branch should evaluate the efforts made by the FDA to streamline the EUA process and make any additional changes that are needed before a potential increase in COVID-19 cases in the fall.

- At an appropriate time, Congress and the Executive Branch should study the development of COVID-19 diagnostic tests by the CDC, including issues related to the development and deployment of the test, to determine whether changes should be made going forward.

- Congress and the Executive Branch should continue to monitor the implementation and use of the large amounts of funding and authorities for diagnostic and antibody testing provided in recent legislation and assess if additional resources and authorities are necessary.

- Congress should conduct oversight into whether the federal government should make additional investments to further increase the volume of testing. The question of additional investments should be examined while considering national testing and surveillance capacity, coupled with other possible investments that may produce higher or complimentary benefits.

- Congress and the Executive Branch should encourage states that the top priority should be testing nursing homes and assisted living residents and staff, whether symptomatic or not.

2. Recommendations for States and Localities

- States, working with the federal government, should determine a testing strategy that utilizes all available testing resources, including rapid point-of-care diagnostic testing, high-throughput laboratory testing, and antibody testing.

    - States should implement and maintain these strategies going into the fall.

    - An effective testing strategy should address the necessary frequency of testing, risk levels for different populations, identifying asymptomatic and mild cases through surveillance, and contact tracing, among other issues.

    - An effective testing strategy in one state may not be effective in another state. Similarly, a strategy for one region of a state may not be effective in other regions within that state. Testing strategies should address regional variances where appropriate.

- States should accurately and continuously monitor their testing supply chain, testing supplies, testing equipment capacity, personnel and testing demand. States need to track testing results and have reliable data collection, reporting and communication methods in or near real time. Without accurate data, existing testing resources may not be properly used.

- While states have formulated testing strategies for the near term, states, in connection with the federal government, should determine whether an increased level of testing may be needed in the fall and, if so, begin to plan to meet the needed capacity.

    - This planning should include determining whether, and, if so, where excess laboratory currently exists within a state that could be used for COVID-19 testing.

- States should have clear plans in place to protect the safety of nursing home residents through regular testing and other means, and limit exposure of nursing home residents to known COVID-19 patients. States that have adopted policies requiring that nursing homes accept COVID-19 positive or suspected positive patients should strongly reconsider these policies and, if not, provide public plans for how they will protect the safety of residents not infected or presumed to be infected with COVID-19.

3. Recommendations for Public Health Laboratories (PHLs)

- PHLs should be modernized to provide access to high throughput yet flexible testing equipment, similar to what large commercial laboratories have. Funding for such equipment could be provided through the epidemiology and lab capacity grants program.

    - PHLs should have a cohesive, secure IT infrastructure in order to increase coordination and communication among the PHLs and private sector laboratories and physicians. Such an infrastructure could not only facilitate improved communication, but also better public reporting of state testing data.

- Congress, the Executive Branch, and the states should consider ways to encourage the submission or more standardized state testing data to the CDC.

- Efforts should also be made by HHS to include PHLs into the new HHS Protect Now platform that currently integrates 187 data sets, including diagnostic testing data, from across the federal, state and local governments, health care facilities, and academia, to help administration officials determine how to mitigate and prevent the spread of COVID-19.

B. Surveillance

- Congress and the Executive Branch should define the intended purpose of a COVID-19 surveillance system (early alert/advanced warning system, forecasting supply needs, contact tracing, tracking cases, etc.) and determine what a comprehensive surveillance strategy should look like to achieve that purpose.

- Legislation recently passed by Congress and enacted into law in response to COVID-19 provides further funding for states, CDC, and other entities that can be utilized for surveillance, and Congress should work to ensure that the laws are implemented as intended, in advance of an increase in COVID-19 cases in the fall.

- Congress has also previously provided funding to improve public health surveillance, including for a multi-year effort to support modernization of public health data surveillance and analytics. Congress and HHS should ensure that the funds are appropriately used to improve surveillance.

- CDC has posted information on its website regarding the reporting of COVID-19 laboratory data. Congress, the Executive Branch, and state health departments should work to ensure that these data collection requirements are being adhered to, and if they are not, work to close those gaps and variations in reporting, as well as examine whether additional requirements are needed to ensure adequate surveillance.

- Through the NMI, CDC is working to enhance NNDSS' ability to provide more comprehensive, timely, and higher quality data for public health decision making. Congress should work with the Executive Branch to evaluate the anticipated timeline of these enhancements and whether they are adequate to meet CDC's COVID-19 surveillance goals.

- Congress, the Executive Branch, and the states should evaluate whether the level of asymptomatic testing being conducted is sufficient to meet CDC's surveillance goals for the U.S. of monitoring the spread and intensity of COVID-19 disease in the U.S.; monitoring for changes in the virus that causes COVID-19; and producing data for forecasting COVID-19 spread and impact. If not, CDC should issue further guidance on the necessary level of asymptomatic testing to achieve these goals.

- With appropriate protections for patients, the private sector, states, and Executive Branch should explore the feasibility of diagnostic testing technology to automatically report results for purposes of disease monitoring, including at-home platforms. This would significantly enhance surveillance efforts by assisting with more timely contact tracing, resource forecasting, and improving the overall public health response.

- CDC recently updated the COVID-19 Case Report Form to standardize the reporting of information on COVID-19 cases. Congress and the Executive Branch

should consider whether these reporting requirements are adequate, and if not, whether additional reporting requirements are needed to ensure complete and actionable data.

- In preparation for a fall outbreak, Congress and the Executive Branch should continue to consider additional short-, medium-, and long-term solutions to the issue of surveillance. These solutions will be even more critical in the fall when influenza season begins again and there is an increase in influenza-like illnesses across the U.S.

- In the short- and medium-term, the capacity created by the private sector to conduct COVID-19 tests should be maintained and expanded.

    - Existing surveillance systems should be evaluated to determine how accurate and comprehensive the data sets are to ensure that the surveillance systems are reliable and actionable for COVID-19. In addition, Congress and the Executive Branch should examine whether a unified and comprehensive national surveillance system dedicated to COVID-19 is needed.

- In the long-term, Congress should evaluate whether a sentinel surveillance system should be authorized and appropriated.

- In addition to considering authorization and funding for a modernized surveillance network, Congress should also consider issues related to data accuracy and security, as well as privacy issues, particularly when patient health information is implicated.