



Summary of March 15, 2020 HHS Coronavirus Testing Call

Secretary Azar hosted a call for testing stakeholders with HHS leadership directly involved in the effort to increase community-based testing for COVID-19. The call was opened by Ambassador Birx, Response Coordinator for the White House Coronavirus Task Force. Senior Advisor to the President Jared Kushner also provided remarks praising the Secretary and his team for their leadership. Secretary Azar summarized the latest information about the overall COVID-19 effort, and then moderated a Q&A session with Assistant Secretary for Health (ASH) Giroir, Assistant Secretary for Preparedness and Response (ASPR) Kadlec, CDC Director Redfield, and FDA Commissioner Hahn. The call was reassuring and optimistic, while acknowledging Americans' frustrations, and delivered factual information about how to access federal resources and the importance of managing expectations.

TOPLINES

1. The White House and Department of Health and Human Services are united in their efforts to support community-based testing, reduce the demand on the acute care system, and overcome any supply chain issues.
2. The recent emergency declarations have created meaningful flexibilities to bring new tests online and minimize supply-chain barriers.
3. The federal government has engaged the private sector in an unprecedented public-private partnership to develop, approve, and deploy high-throughput testing for 2,000 – 4,000 people per site this week. In the meantime, state public health labs in all 50 states have access to the recently improved CDC tests. Specimens will be sent primarily to Quest and LabCorp.
4. State public health departments will develop their own testing priorities, but the federal government is urging that health care workers, first responders, and seniors with respiratory symptoms and fever be tested first. Failure to prioritize testing puts pressure on the existing supply of tests as well as the personal protective equipment used by those providing the tests.
5. All 80 US public health labs are now operational, and 4.5 million tests have been deployed. All 50 states and the District of Columbia all currently have the ability to run tests.

Detailed Summary

Ambassador Birx opened the call by thanking everyone at HHS involved in the federal response and informed attendees about the recently approved Roche and ThermoFisher testing platforms. She asked those involved in testing to expect a marked increase in samples and urged them to ensure they have enough testing supplies (e.g., cartridges, pipettes) to accommodate the increased demand.

Senior Advisor to the President Kushner described the hard work and close collaboration of the White House and HHS, explained the progress that has been made thus far, and foreshadowed exciting news.

Secretary Azar described an unprecedented public-private partnership that is working to unleash private capacity, including the development, approval, and deployment of tests, vaccines, therapeutics, personal protective equipment (PPE) and supply chain support. He also described how the emergency declaration creates new flexibilities, including the ability to do drive-up testing that keeps potentially sick people out of hospitals and reduces demand on the acute care system. It is expected that 2,000-4,000 people per day will be tested in this manner, and this capacity will increase. He reiterated the Vice President's statement that this isn't an all-of-government response, but an all-of-America response, and that state and local governments know best. Lastly, Secretary Azar acknowledged Americans' frustrations regarding testing, and described the federal government's efforts to make testing as easy and accessible as possible.

Question and Answer Session

Secretary Azar: Who should get tested?

ASH Giroir: Two groups: health care workers and front-line responders, and high-risk populations, mainly those over 65 years of age with respiratory symptoms and fever. The fever threshold has been reduced to 99.6°F because seniors are showing a decreased fever response.

Azar: Please describe your work with states.

Giroir: We have spoken with state and local governments to ramp up community testing based on FEMA's PODS approach. Drive-through nasopharyngeal testing will be conducted in the community and processed through Quest Diagnostics and LabCorp so we don't overload hospital labs. 1.9 million high throughput tests will be available this week.

Azar: Normally the FDA approves tests and the CDC deploys them. How is the CDC supporting the response?

CDC Dir. Redfield: CDC provides technical assistance and guidelines. We have provided such to over 80 public health labs in all 50 states. There are 4.5 million tests from the CDC in the field. The FDA has a toll-free number for assistance locating reagents and other supplies. State public health departments will establish their own criteria for who may receive tests through their labs, including the need for physician referral.

Azar: Are the drive-through community-based tests only available to those with a physician referral?

Giroir: Prioritization suggestions are not new barriers or legal restrictions, but we believe they are important to mitigate demand. States may establish their own criteria.

Azar: The FDA has done much to get us where we are today. What else is FDA doing?

FDA Commis. Hahn: The FDA has established a round-the-clock hotline (1-888-463-6332) to help members of the testing community (including test developers) access

information and supplies. The FDA's website also provides them one-stop shopping. **Any hospital or academic medical center, or other CLIA-waived laboratory, can use the laboratory-derived test (LDT) process to develop their own test.** The FDA will require data submission to validate 5 positive and 5 negative tests. The FDA has provided significant guidance about the use of the CDC test, and worked with private manufacturers like Roche and ThermoFisher to bring high throughput testing online. FDA has deemed the New York State Public Health Lab as a surrogate to approve testing conducted by New York labs.

Azar: What about swabbing and transport procedures?

Hahn: FDA granted CDC flexibility about what swabs and transport media may be used for their tests.

Azar: Have you addressed spot shortages of reagents and supplies?

Hahn: There are many different extraction methodologies and platforms that may be used. All of this information is available on FDA's website.

Azar: Does the Strategic National Stockpile have COVID-19 related supplies?

ASPR Kadlec: Yes, we have swabs, PPE, and supportive logistics needed for the response. We are working with FEMA to coordinate the non-medical logistics. Private hospitals and labs have their own supply chain, and we are standing by to support their work. We are also procuring new resources as they are requested, or as shortages emerge. **Stakeholders are reminded that only State Emergency Managers may request support from the stockpile. Please work through your state leadership so they may prioritize requests.**

Azar: What should our expectations be?

Kadlec: We have achieved much over the last week as a result of an unprecedented public-private partnership. Over the last 72 hours, we have spoken with all of the state and local emergency managers. You will see a ramp up and activation of community-based testing this week, with a focus on geographic areas with the greatest need. **Most importantly, we want to keep sick people out of hospitals, keep health care workers healthy, and preserve the supply of available tests and PPE.**

Giroir: Regarding PPE, there is no validated self-test. There may be one soon, but please do not try. If you are testing others, you only need one swab, not two. Because N95s may only be used for one patient, community-based tests will be staffed by people in Tivek suits and PAPRs which may be used for longer periods.

Azar: We are working to make this smooth, but there will be challenges which we solve as they are identified.

Ambassador Birx closed the call by praising the efforts of HHS, and the members of the testing community on the call.