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Subcommittee on Economic & Consumer Policy

COVID-19 Antibody Testing: Uses, Abuses, Limitations, and the Federal Response

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Good morning, Chairman Krishnamoorthi and Members of the Committee. Thank you for the work this subcommittee has already done to shed light on COVID-19 antibody testing challenges, and thank you for the opportunity to be part of this briefing, to contribute to your work to find solutions.

I am an Associate Professor in the Department of Environmental Health and Engineering at the Johns Hopkins Bloomberg School of Public Health. I am also a Senior Scholar and founding member of the Johns Hopkins Center for Health Security. The mission of our multidisciplinary center is to protect people's health from epidemics and disasters and to ensure that communities are resilient to major challenges. My own background is in the biological sciences, specifically in immunology. My work at the center focuses on the scientific response to health security threats, and how to prevent the misuse of biological sciences. I serve on federal advisory committees for the Department of Defense and the National Institutes of Health.

Important for this briefing, I lead our center's ongoing efforts to track the development, market, status, and regulatory environment for COVID-19 antibody and molecular tests. Our team keeps track of all the tests that have Emergency Use Authorization and their accuracy, and explains what these tests are as a resource for a layperson audience. On April 22, we released a report describing potential uses of the tests, areas of uncertainty where additional research is needed, and examples from other countries now beginning

to make use of these tests. This week, we are releasing an additional report describing best practices for serosurveys and limitations for antibody testing for workplaces.

In the course of this work, we have developed several findings about antibody tests:

- **Antibody tests are a useful tool for public health.** With these tests, the true case fatality rate of COVID-19 can be determined from the true prevalence of SARS-CoV-2 infection, as well as the effects of mitigation strategies. Sound decisions may be made about PPE resource allocation, mitigation efforts, and ultimately, vaccine procurement and prioritization. The immediate effectiveness of different public health interventions in limiting virus spread can be assessed and compared, and long-term questions regarding medical sequelae that may require specific interventions may also be addressed.
- **There are significant scientific and practical uncertainties about the meaning of antibody test results, limiting their usefulness to individuals.** It does not appear that reinfections by SARS-CoV-2 are occurring, so for now, it appears that people who have had SARS-CoV-2 infection are protected. However, we don't know what the correlates of immunity are, we don't yet know how long immunity will last, and we don't know whether or what levels of antibodies are important for protection. As research gives us answers to these questions, serology tests could become even more useful.
- **The quality of antibody tests in the US has been highly variable, making the test results difficult to interpret.** There are many antibody tests available which have not been independently validated, and accuracy levels are primarily asserted by the manufacturer. The National Cancer Institute has just started to post some validation data they produced on their website, which is a welcome development.
- **Relying on antibody tests for back-to-work decisions or for “immunity passports” is problematic.** For one, seroprevalence of SARS-CoV-2 is now quite low, so if only COVID-19 positive people were allowed to work, most people would be excluded. Second, there are scientific uncertainties about how long immunity will last, which will make issuing a certificate confusing. Third, the testing could be inaccurate, with significant consequences. A false negative would keep a person from working, but a false positive could lead a vulnerable person to be exposed to SARS-CoV-2, possibly endangering themselves and others. Fourth, requiring immunity for employment could create perverse incentives, leading some to try to get COVID-19 disease in order to be employed. Fifth, it will be difficult to roll-out the distribution of immunity certificates in an equitable and unbiased manner given existing blindspots within vulnerable or minority

communities. Instead, antibody tests need to be part of a suite of public health measures that may be used to decrease risks, along with masks, physical distancing, teleworking, etc. until a vaccine or other medical intervention can be available.

Given these findings, we have several recommendations for the US Government to act:

- 1. The quality of antibody tests should be clear to purchasers; independent validation study results should be public information.**
The FDA, NIH, CDC, and NCI (National Cancer Institute, within the NIH) should release the results of their antibody test validation study so that consumers of antibody tests can determine the quality of the tests they purchase. Validation of serological tests is critical to ensuring that the tests perform as they are intended, and a lack of validation has led to a patchwork of false positives and false negatives across the country, interfering with estimates of seroprevalence and seroincidence. Currently, tests need only to be internally validated for EUA submission, and outside studies have found discrepancies between the accuracy claimed by the manufacturer and their independent tests. On April 4, 2020, it was announced that the NCI would be initiating such independent validation studies, but only 2 out of 15 results have thus far been made public. Updated FDA guidance on May 4, 2020 stated that manufacturers submitting for EUA must also submit tests for independent validation. The NCI is generating this valuable data, and should share it with the public. Some results have begun to be listed in the package inserts for various antibody tests, but it is not transparent to the purchasers of tests nor the individuals who have received tests which tests have been independently validated. Given the variable quality of antibody tests, such independent validation is critical.
- 2. The CDC should coordinate the serosurveys across states and public health departments, and develop a common protocol for states to use.**
All jurisdictions are facing similar challenges, trying to inform policy and mitigation strategies for COVID-19. National coordination of this effort would better utilize resources, improve efficiency and foster data harmonization, and decrease costs. Right now, states are designing and initiating their own studies, but the value would be greater if they had a shared protocol so results may be compared, and so steps may be followed that give the study more statistical power and meaning.
- 3. The US government should create a central repository for serosurveys, similar to the function that ClinicalTrials.gov has for clinical trials.** Given the demand for serosurveys for SARS-CoV-2 infection, sharing of information (including methodologies) is important. While some

details regarding ongoing serosurveys are available currently, most are announced when they are completed. Sometimes, only the results are announced without much methodological detail. Providing information in this way deprives opportunities for one state, for example, to learn from ongoing studies in another state. A central repository, similar to that found in Clinicaltrials.gov, would therefore be a productive resource to include all serosurveys, including their methodology, timelines, and purpose. Such a repository could also be an international resource as well, and could provide connections for others interested in initiating their own, similar studies. The CDC or another HHS agency could host such a site.

4. **Large employers/universities using antibody tests should be strongly encouraged to register their studies in the central repository.** There is potential for the results to inappropriately inform decision making by and about individuals. The FDA and CDC state that serology tests should not be used to inform reopening of schools and businesses. This is particularly fraught because there is insufficient information available about how long immune protection may last, and the quality of antibody tests may lead to many false positives and false negatives. The potential for long term medical sequelae from SARS-CoV-2 infection adds to this concern. Additional protective measures may need to be taken if discrimination based on SARS-CoV-2-specific antibody status occurs, but the first step is to have transparency that these tests are being used. The CDC should develop guidance for large employers/universities using antibody tests, to include how such studies should and should not be interpreted.

In conclusion, the importance and controversy regarding antibody tests is likely to continue, even after a vaccine becomes available, and so it will be important to think long-term. Lingering medical sequelae from SARS-CoV-2 infection could become a public health issue. Past SARS-CoV-2 infection could become a source of employment discrimination. Recovery from COVID-19 may change vaccine prioritization or could lead to one vaccine candidate being a better fit. Vaccination and/or a positive serology test may eventually be required for travel, and so testing will need to be accurate. Though there are important short-term questions necessary to answer to get this disease under control that require antibody testing, we need to be mindful to prepare to collect the information needed to be able to address these long-term issues, as they will likely remain for many years to come.

Thank you to the Committee for including me in this briefing, and thank you for your leadership in guarding against fraud in antibody testing.