



**Testimony**

of

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before the

United States House of Representatives  
Committee on Oversight and Reform  
Subcommittee on Economic and Consumer Policy

regarding

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

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Good morning Chairman Krishnamoorthi, Ranking Member Cloud, and Members of the Subcommittee. I am Dr. Jennifer Rakeam, Assistant Commissioner and Laboratory Director of the Public Health Laboratory at the New York City Department of Health and Mental Hygiene (NYC Health Department). On behalf of Mayor Bill de Blasio and Health Commissioner Dr. Oxiris Barbot, thank you for the opportunity to testify today.

I am here today to discuss the current state of serology testing, including the role serology testing can play in the response to COVID-19, and the challenges of and limitations to this testing. I will also discuss the Food and Drug Administration (FDA) Emergency Use Authorization (EUA) process for evaluating serology tests and ways this process can be improved to protect public health.

### **New York City Context**

The NYC Public Health Laboratory (PHL) has been central to NYC's response to the COVID-19 pandemic. In February, PHL was one of the first laboratories to discover issues related to manufacturing of the Centers for Disease Control and Prevention (CDC) COVID-19 diagnostic test kits. PHL quickly worked with the New York State (NYS) Wadsworth Center Laboratory to deploy a test that was not dependent on the specific extraction kits required by the CDC test that were extremely scarce at the time. Before testing capacity was available at clinical laboratories across the city, PHL provided critical testing capacity for all hospitalized patients in NYC suspected to have COVID-19, including patients at NYC Health + Hospitals, the city's network of public hospitals. With more testing capacity now widely available citywide, PHL has been able to pivot to support other critical aspects of the response, including providing testing for people in higher risk settings, such as homeless shelters and other congregate settings. PHL is supporting a citywide population-based serosurvey and expanding diagnostic testing capacity in NYC to achieve and maintain suppression of this pandemic.

### **Serology Testing Uses and Limitations**

Let me start with the basics. COVID-19 is the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). When infected with SARS-CoV-2, the body begins an immune response and produces antibodies as part of the fight against the virus. A person who has had, and recovered from, COVID-19 will likely have antibodies to the SARS-CoV-2 virus in their blood. Serology tests detect the presence of these antibodies. It's important to note that serology tests do not detect the presence of the SARS-CoV-2 virus itself and cannot be used to diagnose acute infection. Further, serology tests for COVID-19 cannot, at this time, tell us whether someone with SARS-CoV-2 antibodies is immune to, or protected from, a subsequent infection with the virus. We also don't know yet if having SARS-CoV-2 antibodies means that a person is no longer shedding infectious virus and therefore unable to infect others, nor how long the antibodies will remain.

Serology tests can be designed to test for different classes of antibodies. Some serology tests test for IgM antibodies, which develop early in an infection, and others test for IgG antibodies, which are more likely to show up later after the person has recovered, while some test for both classes of antibodies, or can be "total antibody" tests that detect a number of classes of antibodies. Thus, the duration of time since a person was infected with SARS-CoV-2 and the type of test used will impact whether antibodies may be detected. Antibodies detect antigens, parts of proteins and

other molecules made by viruses and other invaders. SARS-CoV-2 is one virus in a family of human coronaviruses, some of which circulate every year and cause the common cold. There are antigens to which our bodies may make antibodies to that are shared across this family of viruses. It is critical to understand both what class or classes of antibodies a test detects, and also whether the test detects antibodies that are specific only to a response to SARS-CoV-2 or detects antibodies to common coronavirus antigens in order to appropriately interpret the results of that test. In addition, the timing of the test relative to the infection is important to the interpretation of the result. Many tests determine whether specific IgG antibodies are present, and this class of antibodies takes time to develop. A test performed too soon after exposure or infection may produce a negative result. Understanding both the specificity of the test (does it only detect antibodies to SARS-CoV-2) as well as the sensitivity of the test (how often will the test detect a known positive) is critical to interpreting results. For example, tests that have a low specificity may produce a false positive test result, reflecting infection with another human coronavirus rather than SARS-CoV-2.

Serology tests that are both sensitive and specific can play a role in providing population-level estimates of the prevalence of past infection. At the individual level, serology tests cannot be used to diagnose COVID-19, in addition, we know little about the significance of an antibody response to the virus. Thus, these tests have limited clinical significance to an individual and should not be used to make decisions about returning to work or about the need for physical distancing, face coverings, or other disease prevention measures. We do not know whether SARS-CoV-2 antibodies confer durable immunity from further infection—that is, whether someone can get COVID-19 again. And while there are some promising studies that show some level of immunity, we don't know how long any immunity will last—months, years, or life-long. Messaging this to policymakers, providers, and the public is critical to ensuring that decisions about whether and how much to relax work, social activity, movement, and other restrictions are made with an understanding of potential health risks attendant thereto. The NYC Health Department has issued guidance to health providers and the public regarding the meaning of serology test results and what they do and do not tell us. Serology testing plays an important role, but public health researchers and scientists need better data on the performance characteristics of the currently available assays to know which are most reliable for detecting past SARS-CoV2 infection and to better understand the human immune response to COVID-19, such as whether seropositivity equates to having long-term protection against the virus.

The NYC PHL is focused on performing serology testing for population-level serosurveys. This month, the NYC Health Department launched a serosurvey as part of a population-based COVID-19 cross-sectional survey, aimed to reach 1,000-2,200 participants between June and September 2020, with plans to repeat the survey with additional groups of participants during subsequent waves of the outbreak. All other serosurveys done in NYC to date have used convenience samples, which are less accurate than population-based surveys, which target a specifically selected group of people that is representative of the overall population of NYC, so this project will enable a more accurate estimation of the SARS-CoV-2 seroprevalence in NYC. The serology testing for this study will be performed at PHL on specimens collected from respondents at their homes. With the data from this serosurvey, we will be able to better estimate the overall infection rate in NYC, and then better estimate overall hospitalization and case fatality rates.

## **Improving Federal Oversight of Serology Tests**

As part of the federal efforts to expand test availability and national testing capacity, on March 25, the FDA issued guidelines allowing the development and market distribution of serology tests as long as test reports include disclaimers stating that the results were not intended to be used as the sole basis to diagnose or exclude SARS-CoV-2 infection. This policy allowed more than 200 serology tests onto the market without being evaluated by the FDA or being granted an EUA, many of which are of poor quality and produce unreliable results. A list of these tests was published on the FDA website. Once this list was published, many companies aggressively and unscrupulously marketed their tests to pharmacies, health care providers, and individuals. Some were even falsely marketed as “FDA authorized” or “FDA approved” when in fact they had not been evaluated or reviewed. They were marketed as “point of care” tests that could be performed in a doctor’s office or other non-laboratory setting. However, any test without an FDA EUA is automatically considered by the Centers for Medicaid Services (CMS) to be “high complexity” and therefore must only be performed in a laboratory with that designation. In addition, because the tests were not authorized by the FDA, the performance of the test would need to be fully validated by the laboratory prior to testing patient specimens. Public health laboratory directors from around the country began pushing for the FDA policy to be reversed, or at least revised. The NYC Health Department sent a letter to health care providers and clinical laboratories warning them not to assume that any of the SARS-CoV-2 serology test kits listed on the FDA website were FDA-authorized or reliable, and none were to be used outside the “high complexity” laboratory setting, if at all.

On May 4, the FDA revised its policy to require all manufacturers with serology tests already on the market to submit an application for an EUA within 10 business days of the announcement (or, for new tests, within 10 days of coming to market) or stop selling their test. It also required a minimum performance threshold for all authorized tests. This means that all of the over 200 tests that were already on the market should have submitted an EUA request by May 18 or be pulled from the market. The enforcement mechanism for this updated policy is unclear. Only 34 tests have been removed from the list on the FDA website, as of June 8. It is unclear whether the manufacturers of all of the other tests have filed an EUA application, and it is concerning that the tests continue to be available while under review by the FDA. Even though the FDA has said these tests are not authorized or approved, the presence of the list on the FDA website continues to give unwarranted credibility. For the non-authorized tests still on the market, there is no available data about their performance or reliability. There is some good news – fifteen high-performing, laboratory-based tests, including one created by the New York State Department of Health Wadsworth Center Laboratory, have received an EUA from the FDA. But it is critical that the FDA strengthen its regulatory process to remove underperforming and/or inaccurate serology tests from its website and the market to ensure the use of only FDA-authorized, reliable tests. This policy needs to be reviewed and scrutinized before the next emergency, as the balance between test regulation and test availability needs to protect the public from both a lack of available reliable tests as well as the availability of unreviewed and unreliable tests.

Chairman Krishnamoorthi and Ranking Member Cloud, thank you once again for inviting me to testify today. And thank you for your continuing advocacy and support in funding state and local public health departments for the COVID-19 response. I look forward to your questions.