



April 20, 2020

The Honorable Stephen M. Hahn, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Commissioner Hahn and Administrator Verma:

On behalf of the American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA), whose members work in regional and community independent clinical laboratories across the United States, we write today to emphasize the need for reliable, accurate, and reproducible serologic tests to respond to the COVID-19 pandemic. In particular, AAB and NILA urge the FDA to enforce manufacturers of COVID-19 serology tests to obtain an emergency use authorization (EUA) and CMS to require proficiency testing for serologic tests through CLIA regulations. While serology tests are less complex than molecular tests, accurate and properly performed serology tests in the midst of a pandemic are enormously consequential. The oversight of these tests should match the risk that faulty or inaccurate serology tests pose to individuals and public health.

Recently, serology testing has captured the attention of the Administration and policymakers as a way to measure an individual's immunity to COVID-19. Discussions have centered on using serology tests as a way to permit non-essential businesses to reopen. With this attention has come a sense of urgency and a desire to get serology tests to market as quickly as possible. To provide regulatory flexibility and to increase serological testing capacity rapidly, FDA released guidance permitting commercial manufacturers to market serology tests after internal validation and without requiring review at FDA. While FDA still has a pathway for serological tests to obtain an emergency use authorization, to date, only four serological tests have been approved through this more rigorous pathway and over 90 test developers have marketed tests without FDA review.¹

AAB and NILA are very concerned that permitting access to minimally regulated serology testing in the midst of the pandemic exposes the public to unneeded risk and encourages unscrupulous companies to advertise false claims and questionable test interpretation criteria. Indeed, companies are already selling serology tests, claiming that the tests are "FDA-approved" or "FDA-authorized."² Inaccurate

¹ FDA Statement. Coronavirus (COVID-19) Update: Serological Tests, at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-tests>

² S.M. Lee, D. Vergano. Coronavirus Antibody Tests Could Help Us Get Back to Normal – or They Could Be the Next Testing Crisis. BuzzFeed News, April 15, 2020, at: <https://www.buzzfeednews.com/article/stephaniemlee/coronavirus-antibody-tests-fda>; C. Clark, COVID-19 Drive-Thru Test Site Shut Down. MedPage Today, April 16, 2020, at: <https://www.medpagetoday.com/infectiousdisease/covid19/85997>; E. Cohen & M. Nigam, 'Crappy' Tests to Check for Past Coronavirus Infection are Flooding the US, Lab Association Says. CNN, April 5, 2020, at: <https://edition.cnn.com/2020/04/05/health/coronavirus-infection-tests/index.html>.

serology tests have significant and potentially deadly consequences, by providing false results to health care providers and patients. Where a false negative SARS-CoV-2 molecular test may lead an individual to unknowingly infect more people, a false positive serology test may cause people to take unwarranted risks in exposing themselves to infection. Data on the nature of immunity following SARS-CoV-2 is still evolving and we are unaware of any data demonstrating that positive test results for IgG or IgM correlates to protective immunity from future infection.

Additionally, because serology tests are likely to be delivered in point of care settings, AAB and NILA are concerned that there will be an increased number of tests that will be “waived” by FDA, and thus the laboratories performing these tests are not subject to external quality controls, such as proficiency testing (PT). Proficiency testing is an important tool for individual laboratories to evaluate and verify the accuracy of the tests performed in their laboratory, and is required by CLIA for high and moderate complexity testing. However, with the unregulated pathway through which many serology tests are coming to market, and the waived tests that FDA has approved, the majority of the tests policymakers will use to determine whether they will reopen their economies will not be subject to any external quality control measures. In addition, the personnel performing waived tests frequently have little to no laboratory training, and some manufacturers of waived tests do not require daily quality control requirements. In addition, there is no mechanism to check and make sure that manufacturers require these internal quality control mechanisms.

AAB and NILA respectfully urge the FDA and CMS to modify its guidance on the development and distribution of serology testing in laboratories, and at the point-of-care, to require an emergency use authorization and to require that the tests undergo adequate external monitoring of accuracy. Further, the intended use for all serology tests should be clearly stated. If it is for screening or for the determination of immune status, a statement as to why the manufacturer believes this claim is justified should be required. Ultimately, the FDA should have, and present, a clear plan for the follow up of all EUA-approved tests (molecular and serologic) for efficacy, including the removal of ineffective tests from the market.

In order for serology testing to fulfill its intended purpose in the country’s response to this pandemic, available testing must be accurate and reliable. AAB and NILA believe that the FDA and CMS should use its regulatory authority to ensure that this is the case.

Sincerely yours,

A handwritten signature in black ink that reads "Mark S. Birenbaum". The signature is written in a cursive, slightly slanted style.

Mark S. Birenbaum, Ph.D.
Executive Director

**American Association of Bioanalysts (AAB) and the
National Independent Laboratory Association (NILA)**

CC: Mike Pence, Vice President, Chair of White House Coronavirus Task Force
ADM Brett Grior, MD, Assistant Secretary for Health, White House Coronavirus Task Force
Deborah Birx, MD, Response Coordinator of White House Coronavirus Task Force