



April 24, 2020

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 Administrator Verma:

On behalf of the National Independent Laboratory Association (NILA), whose members are regional and community independent clinical laboratories across the United States, we write today to emphasize the need for adequate Medicare reimbursement for COVID-19 serology tests. NILA's clinical laboratories continue to work on the front lines of the COVID-19 response by providing accurate and reliable clinical laboratory tests to their communities. As you consider setting reimbursement rates for COVID-19 serology tests, we urge you to account for not only the cost of procuring and performing tests, but also the costs associated with collecting specimens from patients with COVID-19 symptoms, particularly homebound and skilled nursing facility patients.

The Administration has repeatedly emphasized the importance of widespread serology testing to help reopen businesses in communities nationwide. Given the scope and volume of testing that will be needed to achieve that goal, community and regional clinical laboratories will play a critical role in this effort, and NILA's laboratory members are poised and ready to provide serology testing services to their communities. As CMS determines the reimbursement rates for COVID-19 serology tests, NILA urges you to consider the following:

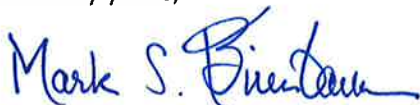
1. Widespread serology testing requires a significant investment by laboratories for equipment, reagents, test kits, and other laboratory supplies to effectively manage the expected volume. While non-COVID-19 serology tests can cost as little as \$0.50 to \$1.50 per test, the COVID-19 serology tests on the market can cost upwards of \$10 per test. Reimbursement rates should reflect the increased cost of COVID-19 serology test kits and the substantial investment needed to purchase and perform these tests.
2. Stay at home orders have increased house calls for NILA members. Laboratory technicians are putting themselves at risk by traveling to homes and skilled nursing facilities to collect

specimens from individuals with COVID-19-like symptoms. While NILA appreciates the increased Medicare fee-for-service specimen collection fees for SNF and homebound patients, these fees are not available for COVID-19 specimens collected from patients enrolled in a Medicare Advantage plan. NILA recommends that CMS account for the increased risk and costs involved in COVID-19 specimen collection by providing a supplementary payment to laboratories that collect COVID-19 specimens from patients covered by a Medicare Advantage plan.

3. Specific personal protective equipment (PPE) that is not typically used in routine specimen collection is needed to collect COVID-19 specimens. This includes N-95 masks, face shields, and protective suits. Adequate PPE will continue to be needed throughout the COVID-19 public health emergency, whether collecting nasal or blood specimens. NILA recommends that CMS consider the additional cost to laboratories to adequately supply their laboratory technicians with the PPE that is required to protect patients, and themselves, from infection.
4. Independent laboratories are on the front line of the COVID-19 response. Laboratorians are essential workers that are at high risk of being exposed while collecting and handling specimens from symptomatic and asymptomatic patients. NILA recommends that CMS compensate laboratory personnel for the risks they are taking by instituting a hazard pay to ensure that trained laboratory personnel remain available and willing to work during the COVID-19 public health emergency.

Our response to the COVID-19 pandemic is unprecedented, and reimbursement for laboratory tests must adjust to this unique testing landscape. Independent laboratories are adapting to meet their community's needs, but will only be able to continue to do so with adequate reimbursement for their testing services. In order for accurate and reliable antibody testing to fulfill its intended purpose in the country's response to the pandemic, when setting rates for serology tests CMS must take into account the expenses incurred by clinical laboratories for the test kits, reagents, quality controls, exposure risks, supplies, and extra time to collect and process COVID-19 specimens.

Sincerely yours,

A handwritten signature in blue ink that reads "Mark S. Birenbaum". The signature is written in a cursive style with a long, sweeping underline.

Mark S. Birenbaum, Ph.D.
NILA Administrator