The United States Must Develop a National COVID-19 Diagnostic Testing and Support Strategy

To mitigate the Coronavirus Disease (COVID-19) pandemic and deter its spread, the American Society for Clinical Pathology calls on the federal government to immediately develop and implement a comprehensive National COVID-19 Diagnostic Testing and Support Strategy. The plan would be used by the federal, state, and local governments as well as healthcare systems, providers, clinical laboratories and others to address patient care needs in this crisis.

On April 30, President Trump signed into law the Paycheck Protection Program and Healthcare Enhancement Act, which includes a number of the recommendations for a national testing strategy that ASCP outlines here. It sets aside $25 billion to support the federal, state and local response to the COVID-19 pandemic and requires the Administration to report to Congress on its strategy to strengthen laboratory test capacity for COVID-19. Shortly thereafter, President Trump released his strategy for improving test capacity, incorporating a number of ASCP's recommendations. These efforts, however, do not provide for the robust response that is necessary to improve test capacity to the point where it can effectively help address the COVID-19 pandemic. There still remains an urgent need for a more coherent national testing strategy and response. To improve the overall federal/state response to COVID-19, ASCP is calling for the creation of a national testing task force, composed of laboratory medicine experts. The Department of Health and Human Services has indicated that the United States will be able to conduct 40-50 million tests monthly by September. Our field can help ensure reliability and accuracy regarding a testing strategy. Supply chain and logistics experts, and federal and state policy-makers can help oversee and coordinate federal and state response efforts, including improving the availability of personal protective equipment and scarce testing supplies and other initiatives detailed below.

This national strategy must address multiple factors that can confront the pandemic and expand our capacity to contain it. It must expand the laboratory testing infrastructure by empowering healthcare systems and clinical laboratories nationwide to provide appropriate diagnostic testing to all patients with or without COVID-19 symptoms, as well as to healthcare workers, first responders and other individuals who may have been exposed to the virus.

The lack of a comprehensive national strategy has resulted in disjointed testing patterns across the United States. The goal for widespread available laboratory testing for at-risk and symptomatic patients is that they receive a reliable diagnostic test when medically appropriate. While developing the United States' pandemic testing capacity, the federal government should also significantly enhance the capabilities of existing surveillance programs to identify outbreaks earlier so that they can be better contained.

Features of this **National Diagnostic Laboratory Testing and Support Strategy** should, at a minimum, include the following elements:

- The public and private healthcare sectors are called on to work in concert to rapidly expand appropriate and expeditious diagnostic laboratory testing for the virus responsible for COVID-19, the SARS-CoV-2 virus, to the at-risk population coupled with contact tracing.
- The federal government should provide funding to diagnostics manufacturers, clinical laboratories and other entities engaged in diagnostics research to support the development of innovative testing devices or components that improve the accuracy and reliability and/or turnaround time of diagnostic or screening tests for COVID-19.
- Congress has guaranteed coverage of testing for COVID-19. This guarantee should be extended to cover diagnostic, screening and other COVID-19-related testing costs by third party payers. Moreover, for uninsured patients, the federal and state governments should pay for these tests and subsidize their COVID-19 treatment/hospital costs.
- Molecular testing is the gold standard for diagnosing COVID-19, and it should be the first test of choice for the diagnosis of acute COVID-19 infection. These rapid diagnostics represent the most accurate test methodologies for the detection of the SARS-CoV-2 virus gene sequences during early stages of infection.

- COVID-19 serology (IgG/IgM) tests should not be used for the acute diagnosis of COVID-19 as it will miss individuals in the early stage of disease progression, including early stage asymptomatic infection, and cannot reliably identify individuals currently infected with the virus.
- The integration of accurate and reliable serologic laboratory testing needs to be coordinated with the appropriate experts to ensure that community exposure, prevalence and reliable markers of individual immunity can be accurately and reliably identified.
- Support for our nation's public health, community, academic and private laboratories needs to include a supply chain distribution model that will ensure that laboratory testing supply shortages (e.g., swabs, viral transport media, etc.) are addressed immediately.
- Optimized supply chain management must also assure the safety of our laboratory teams (and all healthcare professionals) through the timely availability of personal protective equipment (PPE) to include gloves, masks and face shields, gowns or laboratory coats, and respirators (when appropriate) from point of patient specimen collection through laboratory testing.
- Financial support should be provided to CLIA-certified anatomic pathology and clinical laboratories during the pandemic and during its immediate aftermath to ensure continued operations to support continuity of patient care. Without such support, the loss of revenue associated with the suspension of elective testing procedures threatens the financial viability of these laboratories and their ability to help expand our nation's testing capacity.
- The federal government must provide adequate payment for COVID-19 diagnostic and screening tests to ensure clinical laboratories can obtain the financial resources to develop and/or provide these tests.
- Provide support for the use of convalescent plasma as a therapeutic modality for patient care by providing adequate reimbursement. This should include remuneration for appropriate donors to help defray their medical costs.
- Healthcare providers, including pathologists, laboratory professionals and other members of the COVID-19 response healthcare team, are putting themselves at extreme risk and are working long hours providing care for patients in need. The federal government and payers should provide hazard pay, student loan forgiveness and/or other compensation for individuals involved in diagnosing, treating, and screening patients who may have COVID-19 as well as those professionals who perform forensic pathology and death investigations.
- Financial support, in the form of grants and/or loan forgiveness, should be provided to pathologists, pathology residents, medical students, and laboratory professionals including trainees providing services during the COVID-19 pandemic to defray the costs of academic education and clinical training to ensure that these individuals are properly trained to provide efficient and high-quality testing services.
- The federal government should provide the Secretary of Health and Human Services with the authority to compel hospitals, public and private laboratories and other providers to report information, such as laboratory test performance data and patient-specific symptomatic information, pertinent to ensure robust public health surveillance capabilities.