

Statement to the Clinical Laboratory Improvements Advisory Committee on the Preparedness and Response: The Partnership between Clinical Laboratories and Public Health in the age of COVID-19

The College of American Pathologists (CAP) appreciates the opportunity to provide comments to the Clinical Laboratory Improvements Advisory Committee (CLIAC) on the topic of Preparedness and Response: The Partnership between Clinical Laboratories and Public Health in the age of COVID-19. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

As physicians providing services during this unprecedented public health crisis, we have contributed firsthand to helping manage this crisis. The pressures faced by pathologists and the rest of the laboratory workforce are increasing. As a result of the public health crisis, many are seeing an increase in staff burnout. Further, laboratories are imposing hiring freezes, reducing benefits, furloughing employees, and cutting pay. At the same time, now more than ever patients and their treating physicians are relying on the expertise of pathologists to meet increasing diagnostic testing needs. As documented by the media, problems with supplies and communication delayed a ramp-up in testing impacting our most vulnerable communities and frontline health workers, and straining healthcare resources. As such, we are uniquely positioned to provide our perspective on lessons learned. While we welcome this opportunity to offer our initial insights on lessons learned, a comprehensive study of our COVID-19 response should occur before any changes are made to federal policies, guidance, or regulations.

As the COVID-19 pandemic has progress, the collaboration among stakeholders has greatly improved; but a strong public-private partnership is key to ensuring adequate laboratory preparedness in a successful response to future pandemics. Generally, an overarching national government is responsible for broader governance, while the states and cities govern the issues of local concern. For a pandemic, coordination between the federal and states governments is required with clearly defined roles and responsibilities for the federal and state government. Included in these roles and responsibilities should be who has primary responsibility for interfacing with clinical laboratories on infrastructure and resources such as supplies. For consideration, we will focus our comments on three areas:

1. Consistent Uniform Action
2. Regulatory guidance (ie waivers)
3. Coordination federalist systems

Consistent Uniform Action

During COVID-19 clinical laboratories had difficulties managing the differing policy guidance that were released by federal agencies. While it may be difficult given time and resource constraints, the Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), and the Food and

Drug Administration (FDA) should collaborate on guidance to ensure consistency among the respective regulatory guidance to the public. As you know, clinical laboratories worked quickly to ramp up diagnostic testing. To do this successfully, consistent regulatory guidance was needed to support these efforts. While the FDA and the CMS have made recent improvements in this area, initial delays and shortcomings continue to affect the prevalence of testing in the United States. For example, the recent laboratory-developed tests (LDT) policy changes to the EUA process, after the FDA oversaw this process for six-months, has caused confusion for clinical laboratories about LDTs and modified EUA-approved tests. Likewise, with COVID-19 data reporting, clinical laboratories have experienced conflicting guidance and direction from federal officials on how best to comply with the requirements.

In addition, consistent and uniform communications are needed for clinical laboratories to adapt their systems to meet any public health crisis. While the CDC Laboratory Outreach Communication System (LOCS) has been a useful mechanism to get COVID-19 related information, the system is not adequate to address clinical laboratory resource and clinical laboratory needs. Many decisions about resource allocations and infrastructure needs occurred outside of this system through different mechanisms that did not involve key stakeholders. As such, smaller academic medical centers and community laboratories are not getting critical information on supplies and other testing guidance. In the future to increase testing capacity during large-scale public health emergencies, a broader base stakeholder group of clinical laboratories should be included in discussions to advance quality testing, effective reporting, and safe practices to build surge capacity infrastructure.

Regulatory Relief

Once a public health emergency (PHE) is declared certain regulatory requirements are waived or reduced. For example, the FDA emergency use authorization is enacted upon the PHE declaration. A similar process should be enacted for Clinical Laboratory Improvement Amendments (CLIA) to allow laboratories the necessary discretion to determine what is best for their staffs to manage the pandemic. During the COVID-19 crisis, laboratories sought to employ appropriate protocols to reduce the risk of infection among their own teams and to avoid hindering their ability to test and treat patients. The CAP specifically requested a temporary waiver of CLIA requirements so pathologists and other licensed health care professionals could utilize remote review and sign out. Further, the CAP requested the agency postpone inspections of accredited laboratories, which would allow personnel to devote the necessary time to fully verify and validate new coronavirus testing assays and redesign operations to accommodate emerging technologies and testing. We are pleased that both these issues were addressed, but they may not have been were it not for CAP and congressional appeals.

Moreover, given the infectiousness of COVID-19 and to meet the demand for COVID-19 testing of symptomatic patients, clinical laboratories established specimen collection drive-through testing locations. While we welcomed CMS providing flexibility on site locations, the waiver was granted on March 26, 2020 – two weeks after the national emergency declaration, delaying critical testing. Importantly, while we support efforts to streamline administrative procedures for personnel, the CAP strongly believes the current CLIA personnel requirements for testing should be maintained.

Coordination of Federalist Systems

Clarity is needed on the roles of the federal versus state governments in the pandemic response. There has been a lack of clarity on coordination between states and federal government on regulatory guidance, supplies and information. The Administration released a testing plan calling for states to lead many of the testing activities which led states, hospitals, and clinical laboratories to compete for testing supplies. Many laboratories report excess testing capacity and excess instrument capacity but are being constrained by different factors. Laboratory directors cited problems acquiring testing supplies, particularly test kits, plastic pipette tips, swabs, and transport media as the greatest barriers to increased testing and are unclear to whom these issues should be reported too. Initially, directors were told to report to the state health public health offices with minimal success in contacting these officials. In addition, laboratories were unclear on supply procurement prioritization and distribution which resulted in many clinical laboratories implementing three to four testing systems to meet testing demands.

Generally, an overarching national government is responsible for broader governance of larger territorial areas, while the smaller subdivisions, states, and cities govern the issues of local concern. The severity of the next pandemic may drive ultimately who is on the flagpole but at a minimum the officials from the CDC, FDA, CMS CLIA Program as well as should be a part of the federal response team.

Thank you for the opportunity to speak today and the CAP looks forward to working with CLIAC, federal officials, and the clinical laboratory community to develop solutions for COVID-19 and any future pandemics.