Association of Pathology Chairs

Promoting Excellence In Academic Pathology

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Mandy K. Cohen, MD, MPH
Director, Centers for Disease Control and Prevention
Email: CDCExecSec@CDC.gov

Dear Dr. Cohen:

On behalf of the Council of the Association of Pathology Chairs (APC), we send this open letter to express APC's considerable interest in the recent report entitled "Review of the Shortcomings of CDC's First COVID-19 Test and Recommendations for the Policies, Practices, and Systems to Mitigate Future Issues," prepared by the United States' Center for Disease Control and Prevention's (CDC) Advisory Committee to the Director of the Laboratory Workgroup.[1] The APC Council applauds the CDC for embracing a quality-improvement approach in its recent exploration of these issues and for identifying the root causes that led to the initial failure in the SARS-CoV-2 test development and roll-out process. We also note the many excellent recommendations for improvement that are embodied in the report.

The APC supports the culture of quality improvement that the CDC laboratory services seek. In fact, we are interested in serving as partners in ensuring the delivery of high-quality testing to the nation in times of urgent public health emergencies.

The APC is the official organization of academic departments of pathology and laboratory medicine in North America. Accordingly, its members are fully aware of the importance of reliable and accurate laboratory tests. The purpose and foundation of our clinical work is to ensure testing at the highest level of quality and care delivery. The nation's clinical laboratories are directed by the pathologists that we train in our academic health centers where the sickest patients are cared for using tests that we help develop and implement.

At the outset of the COVID-19 pandemic, the APC was deeply frustrated by the Food & Drug Administration's (FDA) dependence on the CDC test kit for SARS-CoV-2 testing to the exclusion of clinical laboratories that were prepared and qualified to help with testing for their hospital systems. When the CDC test kit did not meet performance standards[2,3], the United States' response to the COVID-19 pandemic was seriously delayed compared to other nations, adding to our burden of disease, the backlog of patients needing care, and the public's concern regarding the pandemic response.

We recognize and greatly appreciate the CDC's unique role and tradition as a global resource for identifying and controlling disease outbreaks and providing evidence-based guidance on epidemiology and public health measures. The APC believes that academic clinical laboratories could supplement and strengthen the nation's response if steps were taken now to develop coordination plans between the CDC and academic clinical laboratories to deal with future outbreaks.

We note that several of the report's recommendations describe partnering with academic clinical laboratories, and the APC welcomes this opportunity. We see several areas where the APC could become involved:

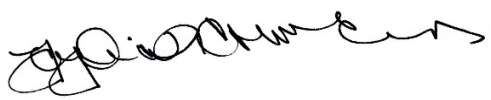
- Recommendation 1 states that the CDC's role and that of the senior laboratory leader must "… involve working with the FDA, state and local public health laboratories, **hospital and academic laboratories,** diagnostic manufacturers, and commercial reference laboratories to plan and operationalize the ability to rapidly develop, scale and deploy needed tests."
- Recommendation 3 states that the CDC's response plans should "integrate with the actions of state and local public health laboratories and health departments, **hospital and academic clinical laboratories**, commercial reference laboratories, and diagnostic test manufacturers, so that tests are not just developed quickly and effectively, but also able to be scaled and distributed…."
- Recommendation 7 states that, "to facilitate the rapid scale-up of testing, the CDC should involve external experts in its review and deployment process for clinical tests for pathogens with pandemic potential… As part of this process, the CDC should incorporate input from external **subject matter experts from academic**, commercial reference, and public health **laboratorie**s."
- Recommendation 8 states "The CDC should develop a 'Centers of Excellence' program comprised of selected and preapproved high functioning public health laboratories, **hospital and academic laboratories**, and commercial reference laboratories."
- Recommendation 10 states "The CDC should lead the standardization of health data collection associated with laboratory tests to improve future public health responses. To meet this objective the CDC should work with APC to help to integrate academic laboratory systems and the data (and metadata) from their testing into the national systems. This was not done during the response to the SARS2-COVID 19 crisis. **Hospital and academic laboratories** should be an essential part of building the national data infrastructure for future public health responses.
- We also enthusiastically support Recommendation #2 for the CDC to establish a new Center that consolidates laboratory support functions with a "focus on clinical laboratory quality, laboratory safety, workforce training, readiness and response, and manufacturing."

The APC welcomes the opportunity to provide input and guidance on implementation of this report, including the recommendations above, perhaps via participation in an external advisory board or as part of the proposed Center of Excellence. The nation's academic clinical laboratories are a unique national resource that can readily be leveraged for expertise and leadership in helping build the network to support the CDC's goals. Indeed, during the SARS2-COVID-19 emergency academic pathology laboratories filled a major role in testing large numbers of patients and in keeping our

hospitals and clinics safe, playing a central role in maintaining a functioning national health system at the height of the pandemic[4,5]. We share with the CDC the common values of creativity and innovation to prepare and care for the most urgent needs, and our laboratories serve many of the country's the sickest patients, including those with the most difficult to diagnose problems.

We encourage you to consider our participation and partnership and look forward to your response.

Sincerely,



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References:

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