



October 19, 2023

The Honorable Bill Cassidy
United States Senate
Committee on Health, Education, Labor
And Pensions
Washington, DC 20510

Dear Senator Cassidy,

The Association for Diagnostics & Laboratory Medicine (ADLM) appreciates the opportunity to provide input regarding your initiative to modernize the Centers for Disease Control and Prevention (CDC). Below are several patient-focused areas we believe the agency should take the lead or be involved in because the areas are important for enhancing the quality of laboratory testing, which will improve children's health, generating evidence-based data to support clinical decision-making, supporting the realization of health equity, and expanding our nation's healthcare workforce.

Improving the Ability to Interpret Pediatric Test Results

The integrity of our healthcare system depends on the reliability of diagnostic tools and methods. For pediatric care, this means the need for pediatric reference intervals, which are used to interpret laboratory test results, are up-to-date, precise, and reflective of the diverse and evolving health needs of our children. Many of the existing pediatric reference intervals fall short. They frequently miss capturing the full spectrum of biological changes in children as they grow, leading to potential misdiagnoses or misguided treatment protocols. Investing in this area means prioritizing an accurate, evidence-based approach to pediatric healthcare and making health equity a reality. Comprehensive pediatric reference intervals will lead to more informed diagnoses, ensuring that children across the nation receive care tailored to their specific developmental stage and health needs. Congress has urged the agency to take up the issue but has not provided the needed funding. The time is now.

Improving Clinical Decision-making

While refining pediatric reference intervals addresses a targeted need, the harmonization of clinical laboratory test results is a broader, yet equally pressing concern. Differences in test results, depending on the method or instrument employed, can lead to variance in diagnoses. A physician should be able to trust that a test result has the same meaning no matter where or how it is generated. The harmonization of cholesterol tests is a testament to the potential benefits of such standardization. Harmonization not only brought consistency in diagnosing heart disease

but led to early interventions, resulting in significant healthcare savings. Dedicating additional resources to this initiative will lay the groundwork for a healthcare system where clinicians across the country can make decisions based on universally accepted and understood metrics, eliminating inconsistencies, and ensuring that every patient, no matter their location or the facility they visit, receives uniform, high-quality care. Harmonized test results are critical to creating an evidence-based network that will better inform our healthcare decision-making process.

As you know the Food and Drug Administration (FDA) has taken bold steps to increase their oversight of Laboratory Developed Tests (LDTs). ADLM is opposed to this increased regulatory burden on LDTs which we believe will result in decreased patient access to testing. We note that if Congress invests in the CDC's ongoing commitment to support effective clinical laboratory testing, which includes providing funding to support the establishment of pediatric reference intervals and to improve test method harmonization, we can greatly enhance the quality of test results without additional FDA oversight.

Strengthening Our Nation's Public Health Infrastructure

Congress needs to improve our public health infrastructure. Past neglect has weakened the CDC's ability to carry out its assigned duties. The CDC, working closely with state and local health departments, should have the capacity to oversee pandemic surveillance activities, such as testing capacity and related supply chain issues, the rate of disease transmission across the nation, recognition and reporting the location of a virus spike or fall, as well as contact tracing data. Moving forward, given the likelihood that COVID-19 will be a health issue for the foreseeable future, Congress should also provide the funds necessary for CDC to not only rebuild the current public health infrastructure but also to prepare for future health crises. It takes significant time to identify and acquire necessary technology, hire and train personnel, develop and implement response strategies, and identify and adopt useful reporting measures. Providing CDC with additional funding to carry out these important duties is central to any public health emergency preparation strategy.

Expanding the Clinical Laboratory Workforce

The public health workforce has been decimated by reduced federal funding and retirements. Local and state health departments have lost approximately one in four staff since 2008 and it is expected to get worse in the ensuing years. We believe an investment of federal resources may encourage more individuals to pursue a public health vocation, thereby helping reduce this shortage. Most COVID-19 testing performed during the pandemic was performed in hospitals and commercial laboratories, which are also experiencing severe personnel shortages. According to the Bureau of Labor Statistics, 72,100 additional clinical laboratory personnel are needed by 2028 just to meet the growing demand for testing services—and this was prior to COVID-19.

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Demand for laboratory testing is likely to continue to increase as the population grows older, point-of-care-testing (POCT) expands, and new tests are developed. Currently, Medical Laboratory Scientists (MLS) programs do not produce enough graduates to fill existing vacancies. Over the next ten years, clinical laboratories need approximately 7,000 laboratory professionals annually, but the MLS programs graduate only 6,000 students a year, leaving a sizeable deficit. One contributing factor to this shortage is the decline in MLS programs. In 1990, there were 720 MLS training programs. Now there are 608—a reduction of 15 percent. More federal funding is needed to reverse this trend.

ADLM is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. ADLM brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

On behalf of ADLM, I would like to thank you for your willingness to engage the healthcare community on this important issue. If you have any questions, please email Vince Stine, PhD, ADLM's Senior Director of Government and Global Affairs, at vstine@myadlm.org.

Sincerely,

A handwritten signature in cursive script that reads "O. Palmer".

Octavia M. Peck Palmer, PhD, FALM
President, ADLM