MONTH DAY, 2021

The Honorable Rand Paul
167 Russell Senate Office Building
Washington, DC 20510

Delivered electronically

Dear Senator Paul:

The undersigned organizations represent institutions, clinical laboratories, physicians, and other professional health care providers involved in using laboratory testing to deliver medical care to millions of patients daily. We write to relay our united support for the Verified Innovative Testing in American Laboratories (VITAL) Act. VITAL would ensure that laboratory developed testing procedures are valued as medical services that provide essential, clinically actionable information to serve clinicians, our patient communities, and the Public Good. Moreover, we are pleased that the bill would initiate a transparent and collaborative process for modernizing the federal Clinical Laboratory Improvement Act (CLIA) regulations by instructing the Centers for Medicare and Medicaid Services (CMS) to hold a public meeting to solicit input from all stakeholders and report to Congress with recommendations to update the regulatory system for laboratory developed testing procedures.

Early in the pandemic, laboratory developed testing procedures performed in clinical laboratories were the only reliable tests for diagnosing COVID-19, delivering results that were vital to hospitals managing patients [1,2,3] and essential to monitoring disease spread nationally. Even with other testing options available, a 2020 study indicated that over a third of laboratories used laboratory developed testing procedures as either their primary way of testing for SARS-CoV-2 or to augment their testing capabilities. This proved crucial and allowed laboratories to quickly adapt testing protocols to accommodate the unfortunate supply chain issues that continue to impact US laboratories.[4] Laboratory professionals acquire expertise through years of education, training and experience in order to apply the most up-to-date medical and scientific knowledge to meet patient needs with laboratory testing. The critical role of these professionals has contributed to our country's ability to respond to this pandemic and past infectious disease outbreaks. Their expertise has also enabled precision medicine and addressed gaps in diagnostic testing in many other areas of medicine impacting therapeutic treatment of patients with cancer, rare diseases, and much more.

Laboratory services are regulated by the CLIA program at CMS. This system has successfully ensured the quality of laboratory developed testing procedures that are currently used in healthcare. However, for years the Food and Drug Administration (FDA) has sought to regulate laboratory developed testing procedures, which are clinical services, under the same approval pathways as medical devices, which are manufactured products. The agency and other proponents of this regulatory change incorrectly assert

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[1] Adalja AA, Toner E, Inglesby TV. Priorities for the US Health Community Responding to COVID-19. JAMA. 2020;323(14):1343–1344. doi:10.1001/jama.2020.3413
[2] Mina MJ, Parker R, Larremore DB. Rethinking Covid-19 Test Sensitivity – A Strategy for Containment. N Engl J Med. September 30, 2020. doi:10.1056/NEJMp2025631
[3] Woloshin S, Patel N, Kesselheim AS. False negative tests for SARS-CoV-2 infection—challenges and implications. N Engl J Med. 2020;383:e38. doi:10.1056/NEJMp2015897
[4] https://www.amp.org/advocacy/sars-cov-2-survey/

that such manufactured products (i.e., In Vitro Diagnostics or IVDs) and laboratory developed testing procedures are equivalent.

When the COVID-related public health emergency was declared, FDA authorized the CDC's problematic test kit for use in diagnosing SARS-CoV-2 and invoked Emergency Use Authorization (EUA) requirements, which suddenly required laboratory professionals to navigate unfamiliar regulations and halted the country's ability to rapidly expand high-quality SARS-CoV-2 testing.

Whereas CLIA oversight of laboratories would have enabled them to use validated laboratory developed testing procedures, the FDA's EUA system created new regulatory barriers, and duplicative and confusing requirements, at a pivotal point in responding to the crisis. These new regulatory barriers, coupled with a flawed CDC test kit authorized through the EUA pathway, meant that the US was without SARS-CoV-2 diagnostic testing for those critical early weeks. CLIA-certified laboratories stood by, ready to act, in January and February 2020, as SARS-CoV-2 was spreading undetected within the US. However, they were unable to do so as only public health laboratories with FDA-authorized CDC test kits were allowed to contribute to SARS-CoV-2 testing. Even after the damage was done and FDA policy allowed clinical laboratories to perform diagnostic testing, continuous and unpredictable modifications of regulatory expectations resulted in many EUA applications sitting at FDA for months, some never reviewed or approved. Given what we have observed during the COVID-19 pandemic, we are convinced that any FDA-centric regulatory proposals of laboratory testing would lead to similar barriers to care in non-emergent healthcare settings.

CLIA has served this country well for decades but has not evolved with science and medicine. The advancements in laboratory medicine and pathology over the past decades warrant that this system be updated to align federal standards with those that most laboratories are already meeting or exceeding today. We are hopeful for the opportunity to work with CMS to modernize CLIA, which would be made possible by the VITAL Act. We stand united in support of modernizing the oversight framework for high complexity clinical laboratory developed testing procedures through reform of the CLIA regulations.

Thank you for hearing our calls to modernize the regulation of laboratory developed testing procedures. We offer our full support as you work to move the VITAL Act. If you have any questions, please contact XXX at XXX.

Sincerely,