



May 14, 2025

The Honorable Robert Kennedy, Jr.
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Kennedy:

The Association for Diagnostics & Laboratory Medicine (ADLM) urges you to reinstate the Clinical Laboratory Improvement Advisory Committee (CLIAC), which advised the Department of Health and Human Services (HHS) on issues involving the Clinical Laboratory Improvement Amendments (CLIA) regulations. These standards regulate more than 300,000 clinical laboratories performing 14 billion patient tests annually.

HHS chartered CLIAC as a federal advisory committee in 1992 to “provide scientific and technical advice and guidance” to the department on the CLIA regulations. The panel served as a forum for federal agencies, industry, medical and professional groups, and patients to discuss timely issues pertaining to the standards and make recommendations for improving them.

Over the past few decades, CLIAC has identified, debated, and provided input on a broad spectrum of issues affecting the quality of testing, personnel requirements, and the precision and frequency of proficiency testing (PT), and other aspects of the patient testing process. These suggestions were incorporated in CLIA final rules published by the Centers for Medicare and Medicaid Services (CMS) (See the 1/24/03; 7/11/22; & 12/28/23 Federal Registers).

Similarly, CMS has included many CLIAC recommendations in the State Operations Manual (e.g., modifications to the Quality Management System requirements) used by inspectors to ensure the standards are up-to-date and that testing is performed in a safe and effective manner. This ongoing partnership between the differing stakeholders has improved testing and contributed to better patient care.

It is important to note that the CLIA program is funded by \$80 million in user fees collected from the laboratory community. These funds are spent on educating clinical laboratories about best practices, managing the quality assurance and accreditation programs, conducting inspections, and funding CLIAC. Given the vital role that laboratory testing plays in diagnosing and caring for patients, ADLM urges you to reinstate CLIAC.

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ADLM is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. ADLM brings together 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 clinical laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

We look forward to collaborating with you on this critical issue. If you have any questions, please email Vince Stine, PhD, ADLM's Senior Director of Government and Global Affairs, at vstine@myadlm.org, or Evan Fortman, MPA, ADLM's Manager of Government Affairs at efortman@myadlm.org.

Sincerely,

A handwritten signature in blue ink, appearing to read "Anthony A. Killeen".

Anthony A. Killeen, MD, MSc, PhD
President, ADLM