June 30, 2025

Robert F. Kennedy, Jr.
Secretary, Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Kennedy,

On behalf of the undersigned organizations representing the nation's clinical and public health laboratories, we urge you to reinstate the Clinical Laboratory Improvement Advisory Committee (CLIAC) and schedule a November 2025 meeting. CLIAC provides recommendations to the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA) on relevant updates to the Clinical Laboratory Improvement Amendments (CLIA) regulations to assure accuracy and reliability of laboratory test results that inform patient care and treatment.

The Public Health Services act authorizes the HHS Secretary to establish standards that "ensure consistent, accurate, and reliable test results" and CLIAC is the most effective and efficient way to achieve that goal. Laboratory science has moved forward by leaps and bounds since the implementation of CLIA. CLIAC fills a huge gap between the federal agencies and the frontline of laboratory testing. Without CLIAC, there are no opportunities to discuss the improvements needed to laboratory testing services and practice. Without a forum to discuss the needed changes, CLIA regulations will become outdated and disconnected from current laboratory practice. Ultimately, it is the patient who suffers from lower quality testing services and the entire health care system is eroded.

Through the years, CLIAC has been proven to be an irreplaceable forum for the three federal agencies to hear directly from frontline experts who represent various sectors of clinical laboratory communities and advise on needed revisions to federal regulations governing clinical laboratory science. **CLIAC should be reinstated, and the November 2025 meeting should be scheduled so subject matter experts can continue communicating about issues affecting laboratory science with the federal agencies that govern CLIA to protect patients' safety.** This will ensure that healthcare providers will continue to receive accurate and reliable test results that guide their patients' treatment.

The work of CLIAC can greatly support your efforts to make Americans healthy again. The undersigned organizations strongly urge you to restore CLIAC and support its work to make sure clinical laboratory regulations remain adequate to protect patient safety and make life-saving improvements to current clinical laboratory practice, supporting diagnoses of medical conditions from acute infections to chronic diseases.

Sincerely,

American Association of Pathologists' Assistants
American College of Medical Genetics and Genomics
American Medical Technologists
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
American Society for Clinical Pathology Board of Certification
American Society for Histocompatibility and Immunogenetics
American Society for Microbiology
American Society of Cytopathology
American Society of Hematology
Association for Academic Pathology
Association for Diagnostics & Laboratory Medicine
Association for Pathology Informatics
Association of Public Health Laboratories
Big Cities Health Coalition
Clinical and Laboratory Standards Institute
Commission on Laboratory Accreditation, Inc.
College of American Pathologists
Infectious Diseases Society of America
National Accrediting Agency for Clinical Laboratory Sciences
National Association of Medical Examiners
National Society for Histotechnology
National Society of Genetic Counselors
Philippine Association of Medical Technologists-USA, Inc.
Project Santa Fe Foundation - Lab 2.0
Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) Collaborative Community

Addendum

Examples of recent CLIAC actions and recommendations.

CLIAC provides scientific and technical advice and guidance that improves laboratory quality and practice. The advisory group consists of representatives from various specialties at public health laboratories along with hospital, commercial and academic clinical laboratories. These individuals work on the frontlines of testing and deliberate on issues important to quality laboratory diagnostics and make expert recommendations to the federal agencies that oversee CLIA. For example, CLIAC meetings frequently discuss the ten CLIA standards laboratories most often fail to meet. Many of these deficiencies are consistent across time and organizations, indicating long-lasting and deeply rooted problems in laboratory practice. In response, CLIAC has deliberated on obstacles to compliance and advised the agencies where clarification is needed in the CLIA interpretive guidelines. The group has also discussed additional needs and resources, such as CDC-organized training for laboratory directors and a CLIA toolkit specific to correcting these laboratory shortfalls.

CLIAC members research laboratory science developments to support informed recommendations. CLIAC workgroups are charged with answering specific questions and providing input to CLIAC for their consideration. For example, the CLIA Personnel Regulations Workgroup provided input on modifying personnel requirements to ensure appropriate education for personnel performing and supervising laboratory testing. The information was considered and CLIAC ultimately recommended modifications to the CLIA regulations for personnel requirements. These recommendations were evaluated by the federal agencies and later incorporated in the CMS Final Rule: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories.

An important role of CLIAC is to consider technological advances to laboratory sciences and recommend needed updates to CLIA standards to ensure laboratory practices remain modern and efficient. The regulations date back to 1988 when laboratory procedures did not utilize recent advances in clinical testing such as genomic sequencing or the use of artificial intelligence and machine learning (AI/ML) in laboratories. At its meetings in 2024, CLIAC was considering the role of AI/ML in laboratory testing and what standards assure knowledgeable scientists were performing and interpreting the tests.