

November 2, 2021

Reynolds M Salerno, PhD
Director, Division of Laboratory Systems
Designated Federal Official, Clinical Laboratory Improvement Advisory Committee
US Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Dr. Salerno:

We, the undersigned organizations, urge the Clinical Laboratory Improvement Advisory Committee (CLIAC) to conduct a public meeting to discuss the modernization of the CLIA regulations for laboratory developed tests (LDTs). In recent years, there has been much discussion about what defines an LDT, how they are used in patient care, and what is the appropriate level and channels of oversight for these tests. Given that LDTs are regulated under CLIA, we believe CLIAC is the appropriate venue for addressing these issues.

Since the CLIA standards were first promulgated in 1992, there have only been modest changes to the regulations. Since 2018, CLIAC has identified several areas in need of modernization, including the personnel standards, the use of laboratory data in medical decision-making, and the regulation of new technologies, such as next generation sequencing. We applaud these efforts. Given the ongoing concerns and discussions pertaining to LDTs, we recommend that CLIAC expand these efforts to include a comprehensive assessment of LDTs.

At its April 2021 meeting, CLIAC laid the foundation for such a discussion when it reviewed the role of LDTs within the context of the COVID-19 pandemic. We recommend that the committee build upon that conversation by initiating a discussion on the broader use of LDTs and gathering information on how CLIA oversight can be updated to ensure that physicians, other healthcare professionals, and patients continue to have access to high quality, accurate LDTs.

Among the various topics that could be addressed are what constitutes an LDT, what patient risks are posed by LDTs, whether LDTs should be stratified based on risk, and whether clinical validity should be required and, if yes, how it should be demonstrated. We hope that such a meeting will start to resolve the confusion and conflict surrounding this issue, lead to better patient care, and continue the process of modernizing CLIA.

Our groups look forward to working with you on this important issue.

Academy of Clinical Laboratory Physicians and Scientists
American Association for Clinical Chemistry
American College of Medical Genetics and Genomics
American College of Rheumatology
American Hospital Association
American Medical Association
American Society of Hematology
American Society of Transplantation

Association for Molecular Pathology
Association of Pathology Chairs
Association of Pediatric Hematology/Oncology Nurses
Clinical Immunology Society
Lyme Disease Association
National Society for Genetic Counselors
Pan American Society for Clinical Virology
Pediatric Endocrine Society
Society for Reproductive Investigation

Cc: Valerie L. Ng, MD, PhD, Chair, CLIAC
Collette Fitzgerald, PhD, CDC
Monique Spruill, CMS
Timothy Stenzel, MD, PhD, FDA