

April 10, 2025

The Honorable Shelly Moore Capito
Chair
Appropriations Subcommittee on
Labor, Health and Human Services,
Education, and Related Agencies
United States Senate
Washington, D.C. 20510

The Honorable Tammy Baldwin
Ranking Member
Appropriations Subcommittee on
Labor, Health and Human Services,
Education, and Related Agencies
United States Senate
Washington, D.C. 20510

The Honorable Robert Aderholt
Chair
Appropriations Subcommittee on
Labor, Health and Human Services,
Education, and Related Agencies
United States House of Representatives
Washington, D.C. 20515

The Honorable Rosa DeLauro
Ranking Member
Appropriations Subcommittee on
Labor, Health and Human Services
Education, and Related Agencies
United States House of Representatives
Washington, D.C. 20515

Dear Chairs Moore Capito, Aderholt, and Ranking Members Baldwin and DeLauro,

As you and your colleagues develop the Fiscal Year (FY) 2026 Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations bill, we respectfully request that funding for the Centers for Disease Control and Prevention (CDC) Clinical Standardization Programs be increased to enable the agency to further its essential work in standardizing or “harmonizing” the reporting of clinical laboratory test results. Investment in these programs will yield significant dividends improving patient care, driving down costs, and is foundational to the advancement of next-generation healthcare technology.

Clinical laboratory testing plays an essential role in medical decision-making, providing essential data for diagnosis, treatment, and disease management. However, test results obtained from one laboratory are often not directly comparable to the same test performed at another, even if both results are accurate within their respective methodologies. These variations in different laboratory results can introduce confusion in diagnosis, improper treatment decisions, and raise costs across the healthcare system. This problem is often apparent with testing performed for chronic diseases such as cardiovascular disease, diabetes, kidney and bone diseases, certain cancers, and conditions important to women’s health like polycystic ovary syndrome (PCOS).

As healthcare data analytics and AI-driven decision support tools become increasingly integrated into clinical practice, harmonization of laboratory data is essential. More than 70 stakeholder organizations in the Food and Drug Administration’s Standardization of Lab Data to Enhance Patient-Centered Outcomes Research and Value-Based Care (SHIELD) collaborative have recognized the critical importance of this issue. Additionally, a recent report issued by the

Page Two
April 10, 2025

Bipartisan Congressional Task Force on Artificial Intelligence has further underscored the critical need for uniform standards in healthcare, stating in its key findings that "the lack of ubiquitous, uniform standards for medical data and algorithms impedes system interoperability and data sharing. If AI tools cannot easily connect with all relevant medical systems, their adoption and use could be impeded."

By establishing robust standardized frameworks, CDC's harmonization efforts complement private-sector innovation and help in vitro diagnostics (IVD) manufacturers and clinical laboratories develop more accurate tests and remain globally competitive. The investments Congress has made have allowed CDC Clinical Standardization Programs to improve test quality, improve testing devices, and collaborate with strategic partners to expand standardization and drive adoption.

To build on this momentum, the undersigned organizations urge Congress to provide an additional \$7.2 million for the CDC's Environmental Health Laboratory in FY 2026. Continued support will strengthen private-sector innovation, support advances in innovative healthcare technology, and improve health outcomes. We appreciate your consideration of this request and stand ready to serve as a resource on laboratory testing harmonization.

Sincerely,

American Medical Technologists

American Society for Clinical Laboratory Science

American Society for Microbiology

American Thyroid Association

Association for Diagnostics & Laboratory Medicine

Association for Molecular Pathology

Association of Public Health Laboratories

Association of Schools and Programs of Public Health (ASPPH)

Big Cities Health Coalition

COLA, Inc.

College of American Pathologists

Infectious Diseases Society of America

Laboratory Corporation of America Holdings

National Association of Pediatric Nurse Practitioners

PCOS Challenge: The National Polycystic Ovary Syndrome Association

Pediatric Endocrine Society

Quest Diagnostics

Roche Diagnostics

Siemens Healthineers Diagnostics

Society for Reproductive Investigation