

April 5, 2024

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

The Honorable Shelley Moore Capito  
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 Chair Baldwin, Chair Aderholt, and Ranking Members Moore Capito and DeLauro:

As you and your colleagues work on the Fiscal Year (FY) 2025 Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations bill, we respectfully request that you increase funding for the U.S. Centers for Disease Control and Prevention (CDC) to continue its efforts to harmonize the reporting of clinical laboratory test results.

The undersigned organizations believe that every patient should have access to dependable and accurate clinical laboratory test results and that those test results should be harmonized. The CDC is doing incredible work harmonizing the results for several tests, and we believe with continued funding CDC could expand its efforts—benefiting clinicians and patients alike and contributing to overall efficiencies in public health and healthcare.

Clinical laboratory testing plays an important role in medical decision-making. As the healthcare delivery system moves towards a more integrated model where health information will be shared amongst providers, patients, and payers, laboratory data will be the key piece of health information that will be used to improve the quality of care using clinical guidelines, performance measures, and electronic health records.

For most laboratory tests, however, a gold standard either does not exist or is not readily applied. Unfortunately, this means that a result from one clinical test method may present a different numeric value compared to another clinical test method measuring the same patient sample, even though each result is accurate within the context of its own method. Experts call this a lack of harmonization. A test that is harmonized (or standardized) provides the same result regardless of the method or instrument used or the setting where it is performed.

Establishing standardized data elements and terminologies is essential to ensure consistent interpretation of laboratory results. Harmonization is also a key requirement for interoperability, enabling efficient data integration and exchange within the healthcare delivery system. Harmonization will ensure that laboratory data can not only be shared, but also meaningfully utilized - improving patient care, and supporting research.

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Congress has supported CDC's harmonization efforts over the past several years and the agency has responded by producing several breakthroughs. Increased funding enabled the CDC Clinical Standardization Programs to:

- Produce and distribute reference/harmonization materials for clinical standardization programs, utilized by clinical laboratories and medical device manufacturers in the US and countries around the world, that improved the accuracy of chronic disease biomarker testing used in patient care and public health.
- Substantially increase the number of harmonized biomarkers (from 10 in 2014 to 26 in 2022) used by physicians to diagnose and treat diseases such as cardiovascular disease, diabetes, certain cancers, blood pressure, bone disease, kidney disease, and developmental diseases.
- Expand harmonization/standardization program activities by improving point-of-care-testing devices used in clinical and in-home settings, such as those used by individuals with diabetes, and engaging additional strategic partners, such as patient advocacy groups and payers, through outreach and education.
- Increase the number of method performance evaluations of laboratories/manufacturers and issue more performance certificates that let manufacturers, physicians, and other healthcare providers know about the accuracy and reliability of tests currently in use.

In just a few short years, CDC has managed to make great strides in this area. To continue this advancement, we recommend that for FY 2025 the CDC be appropriated an additional \$7.2 million for activities directed by its Environment Health Laboratory. We believe this continued investment in CDC will lead to future cost savings and better health outcomes. The undersigned groups stand ready to be an ongoing resource to members of Congress on laboratory testing harmonization and we appreciate your consideration.

Sincerely,

American Clinical Laboratory Association  
American Medical Technologists  
American Society for Clinical Laboratory Science  
American Society for Clinical Pathology  
American Society for Microbiology  
American Society of Hematology  
American Thyroid Association  
American Urological Association  
ARUP Laboratories  
Association for Diagnostics & Laboratory Medicine  
Association for Molecular Pathology  
Association of Maternal & Child Health Programs  
Association of Public Health Laboratories  
Association of Schools and Programs of Public Health  
Big Cities Health Coalition  
COLA, Inc.

College of American Pathologists  
Endocrine Society  
Infectious Diseases Society of America  
Laboratory Corporation of America Holdings  
National Association of Pediatric Nurse Practitioners  
National Network of Public Health Institutes  
PCOS Challenge: The National Polycystic Ovary Syndrome Association  
Pediatric Endocrine Society  
Quest Diagnostics  
Roche Diagnostic Corporation  
Siemens Healthcare Diagnostics  
Society for Reproductive Investigation