

March 22, 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 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