

March 17, 2021

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

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

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

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

Dear Chairwoman Murray, Chairwoman DeLauro, and Ranking Members Blunt and Cole:

As you and your colleagues work on the Fiscal Year (FY) 2022 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 after funding the program in FY'21.

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.

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Congress has showed its support for CDC's harmonization efforts over the last several years and CDC has responded by producing several breakthroughs. Past funding has resulted in expanded harmonization and standardization activities that improve detection and management of hormone disorders, kidney disease, cancer, and heart disease. Specific examples of CDC's progress include:

- Producing and distributing reference/harmonization materials for clinical standardization programs and to 30 countries for chronic disease biomarkers
- Developing reference methods for highly accurate measurement of biomarkers used for the diagnosis of multiple diseases, including bone, kidney, diabetes, cardiovascular, endocrine and cancers
- Expanding outreach of harmonization/standardization programming to non-traditional markers, point-of-care-testing devices and patient and payor organizations.
- Conducting method performance evaluations for laboratories/manufacturers and issuing performance certificates.

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 2022 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 yours,

American Association for Clinical Chemistry
American Clinical Laboratory Association
American Medical Technologists
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
American Urological Association
ARUP Laboratories
Association of Public Health Laboratories
Clinical Laboratory Management Association
COLA
College of American Pathologists
Endocrine Society
Laboratory Corporation of America Holdings
Mayo Medical Laboratories
PCOS Challenge: The National Polycystic Ovary Syndrome Association
Pediatric Endocrine Society
Quest Diagnostics
Roche Diagnostics
Siemens Healthineers
Society for Reproductive Investigation
Thermo Fisher Scientific