

February 20, 2020

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

The Honorable Patty Murray
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 Chairman Blunt, Chairwoman DeLauro, and Ranking Members Murray and Cole:

As you and your colleagues work on the Fiscal Year (FY) 2021 Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations bill, we respectfully request you maintain funding for the U.S. Centers for Disease Control and Prevention (CDC) to continue and expand its efforts to harmonize the reporting of clinical laboratory test results after funding the program in FY'20. 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 has already done incredible work harmonizing the results for a limited number of tests, but we believe with additional 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 through the use of 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 provides the same result regardless of the method or instrument used or the setting where it is performed.

When test results are not harmonized, the entire continuum of patient care can be affected in profound—but not always obvious—ways. For example, medicine is moving toward evidence-based guidelines to ensure the best care for the population, and often these guidelines are anchored in laboratory test results. However, if the test results on an individual patient are obtained using a method that is not harmonized with the method that was used to produce the guideline, physicians may inadvertently choose the wrong care path for their patient. Benefits from harmonization include fewer medical errors and lower healthcare costs by eliminating unnecessary follow-up diagnostic procedures and treatments. CDC, medical device manufacturers and the laboratory community have already teamed up to harmonize some

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important tests like cholesterol for heart disease and hemoglobin A1c for diabetes. Now is the time to build on those advances and harmonize additional testing results.

In order to continue to move this important initiative forward we recommend that for FY 2021 the CDC be appropriated an additional \$7.2 million for activities directed by the Environmental Health Laboratory. Harmonized test results will ensure that clinical guidelines based on the results of laboratory tests lead to appropriate care by enhancing the reliability of screening to detect diseases early, by producing more accurate diagnoses, and by preventing treatment errors. In addition, harmonized clinical laboratory test results will prevent unnecessary — and expensive — follow-up diagnostic procedures and treatments that could arise due to misinterpretation of those results.

We believe this 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
Thermo Fisher Scientific