

March 3, 2017

The Honorable Roy Blunt  
Chairman  
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 Tom Cole  
Chairman  
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 Chairmen Blunt and Cole, and Ranking Members Murray and DeLauro:

As you and your colleagues work on the Fiscal Year (FY) 2018 Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations bill, we respectfully request additional 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. 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 a majority of 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.

March 3, 2017

Page Two

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 as a way 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 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 December 2014, the House and Senate passed, and the President signed into law, the Consolidated and Further Continuing Appropriations Act of 2015. In the accompanying report language, the two chambers identified harmonizing of clinical laboratory test results as a key priority, stating: “Laboratory professionals use a variety of test methods to obtain accurate and informative results to diagnose and treat patients, which may result in the reporting of different numeric values for the same test. CDC is urged to partner with the private sector in “harmonizing” clinical laboratory test results.” Furthermore, the House Appropriations Committee included report language to accompany the FY 2017 Labor, HHS, Education Appropriations bill which instructed the CDC to provide the Committee with an update on the CDC’s activity on the Harmonization of Test Results in the agencies’ Fiscal Year 2018 budget request to Congress.

In order to move this important initiative forward we recommend that for FY 2018 the CDC be appropriated an additional \$9.2 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  
Laboratory Corporation of America Holdings  
College of American Pathologists  
Pediatric Endocrine Society  
Quest Diagnostics  
Roche Diagnostics  
Siemens Healthcare Laboratory Diagnostics  
The Association of Genetic Technologists  
Thermo Fisher Scientific