

February 26, 2016

The Honorable Thad Cochran  
Chairman  
Committee on Appropriations  
United States Senate  
Washington, D.C. 20510

The Honorable Harold Rogers  
Chairman  
Committee on Appropriations  
United States House of Representatives  
Washington, D.C. 20515

The Honorable Barbara Mikulski  
Vice-Chairwoman  
Committee on Appropriations  
United States Senate  
Washington, D.C. 20510

The Honorable Nita Lowey  
Ranking Member  
Committee on Appropriations  
United States House of Representatives  
Washington, D.C. 20515

Dear Chairmen Cochran and Rogers, and Ranking Members Mikulski and Lowey:

As you and your colleagues begin work on the Fiscal Year (FY) 2017 appropriations bills, 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. However, for a majority of laboratory tests there is not a gold standard for reporting comparable results. 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, although each may be 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, as medicine moves toward evidence-based guidelines as a way to ensure the best care for the population, often these guidelines are anchored in laboratory test results. However, if the test results do not align with the guideline, physicians may inadvertently misinterpret the results. 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 critical 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.

On December 14, 2014, the House and Senate passed, and the President signed into law, the Consolidated and Furthering 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.*” In order to move forward with this directive from Congress we recommend that for FY 2017 the CDC be appropriated an additional \$9.2 million for its environmental health laboratory.

Harmonized test results will ensure that clinical guidelines calling for the use 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 based on misinterpretation of those results.

As you begin your work on the FY 2017 appropriations process we strongly encourage you to make harmonization of test results a priority. We believe this investment in CDC will result in 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  
Clinical Laboratory Management Association  
College of American Pathologists  
Laboratory Corporation of America Holdings  
Roche Diagnostics  
Siemens Healthcare Laboratory Diagnostics