

September 12, 2016

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

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

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

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

Dear Chairman Cochran, Ranking Member Mikulski, Chairman Blunt and Ranking Member Murray:

As you work on spending legislation for fiscal year (FY) 2017, we urge you to ensure that the report language regarding the harmonization of clinical laboratory testing results—that was included in the House Appropriation Committee’s Labor, HHS, Education and Related Agencies appropriations bill—is included in the funding package. The report language requests that the Centers for Disease Control and Prevention (CDC) describe its ongoing and planned efforts for the harmonization of clinical laboratory test results in its 2018 budget submission.

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.

As the healthcare delivery system moves towards a more integrated model, laboratory data will be critical to improving the quality of care through the development and use of clinical guidelines and performance measures. However, for a majority of laboratory tests there is not a gold standard for reporting comparable results. This means that test methods may report different numeric values for 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.

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 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

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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.

As you work on the end-of-the-year spending bill, we strongly encourage you to include the harmonization report language in the final package. We believe further CDC activities in this area 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 the harmonization of laboratory tests 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
Association of Public Health Laboratories
College of American Pathologists
Clinical Laboratory Management Association
Laboratory Corporation of America Holdings
Pediatric Endocrine Society
Quest Diagnostics
Roche Diagnostics
Siemens Healthcare Laboratory Diagnostics
The Association of Genetic Technologists
Thermo Fisher Scientific