



STATEMENT

**of the
American Association for Clinical Chemistry
to the
U.S. House of Representatives
Committee on Appropriations Labor, Health & Human Services, and Education
Subcommittee**

Re: FY2022 Budget Requests

**Presented by David Grenache, PhD, D(ABCC)
President, AACC**

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The American Association for Clinical Chemistry (AACC) welcomes the opportunity to provide testimony to the House Appropriations Subcommittee on Labor, Health & Human Services, and Education regarding our nation's fiscal year (FY) 2022 budget priorities. AACC and its partners are urging the subcommittee to support two initiatives vital to improving the quality and efficacy of healthcare in the United States:

- **Improving Pediatric Reference Intervals** - \$10 million for the Centers for Disease Control and Prevention, Division of Laboratory Services, Environmental Health Laboratory to improve the quality of pediatric reference intervals used by health practitioners to diagnose, monitor, and treat children.
- **Harmonizing Clinical Laboratory Test Results** - an additional \$7.2 million (\$9.2 million in total) for the Centers for Disease Control and Prevention, Division of

Laboratory Services, Environmental Health Laboratory to continue its ongoing efforts to harmonize the reporting of clinical laboratory test results, which is the vital to providing better, more consistent healthcare in the United States.

Improving Pediatric Reference Intervals

AACC, the American Academy of Pediatrics, the Children's Hospitals Association, and 30 other organizations have written to the subcommittee urging additional funding for the Centers for Disease Control and Prevention (CDC) to improve the quality of pediatric reference intervals (PRIs) - the range of numeric values expected in a healthy child – available to health practitioners to care for their young patients.

When making a diagnosis, the healthcare professional considers a laboratory test value within the context of a reference interval. If the test result falls outside of the defined reference interval for a healthy child – either higher or lower – the practitioner may order a medical intervention to address a health condition or change an ongoing treatment protocol. If the diagnosis or treatment change is incorrect for any reason, including an inaccurate reference interval, it could result in patient harm. Therefore, it is critical that the range of values used by practitioners to interpret test results are accurate.

Whereas the reference intervals for adults are generally reliable, there is considerable inconsistency and large gaps in the ranges available for children. Healthcare practitioners need reference intervals reflective of healthy children at each unique stage of physical development from birth through adolescence to adulthood. In addition, the intervals must also take into consideration any variations due to biological factors, such as ethnicity and gender.

Accurate and actionable PRIs are particularly important for our youngest patients, who are often unable to verbally communicate their symptoms. Unfortunately, most laboratories are unable to obtain enough samples from a diverse, healthy population of children to develop their own reference intervals.

Congress recognized the importance of this issue when in the accompanying report language to the *Further Consolidated Appropriations Act of 2020* it requested CDC to develop and submit a plan for improving PRIs. The agency outlined its plan in the Department of Health and Human Services fiscal year 2021 congressional justification to Congress. The plan calls for the CDC to employ its existing infrastructure to initiate and advance this vital work. According to CDC, it can:

- collect clinical samples through its National Health and Nutrition Examination Survey (NHANES), which has the organization and expertise to collect specimens from healthy children; and
- utilize its Environmental Health Laboratory (EHL) to generate the reference intervals for children and disseminate the information to clinical laboratories. EHL has developed reference intervals in the past.

AACC and its partners support providing CDC with an additional \$10 million to improve the quality of PRIs critical to caring for our nation's children.

Harmonizing Clinical Laboratory Test Results

Another issue that AACC and its allies request your assistance with is the harmonization of clinical laboratory test results. Laboratory test methods provide accurate test results, but different methods generate different numeric values. With different methods in use across the healthcare system, lack of harmonization makes it difficult to develop widely applicable clinical guidelines or performance measures. It also complicates data aggregation, which limits the development of tools to better inform health decision-making.

Tests that are harmonized (or standardized) provide the same numeric value for a condition regardless of the method or instrument used or the setting where the tests are performed. An early example of harmonization is cholesterol, which is widely utilized by the medical community to diagnose heart disease. A 2011 study published in *Preventing Chronic Disease* reports that early drug intervention based on cholesterol levels saved the health system \$338 million to \$7.6 billion annually between 1980 – 2000.¹ Harmonization can improve patient care while also saving money.

In recent years, the subcommittee and Congress have supported expanding CDC's harmonization efforts, resulting in new activities to improve the detection and management of hormone disorders, kidney disease, cancer, and heart disease.

¹ Hoerger TJ, Wittenborn JS, Young W. A cost-benefit analysis of lipid standardization in the United States. *Preventing Chronic Disease* 2011; 8: A136

With additional funding, CDC will be able to expand its harmonization activities to develop materials for non-traditional biomarkers, such as apolipoproteins, and the assessment of point of care testing devices that are increasingly being used by healthcare providers and patients.

AACC and its partners respectfully request that the subcommittee provide an additional \$7.2 million (\$9.2 million in total) for the CDC to continue and advance its harmonization activities. Congress has provided \$2 million annually for this program since FY18. The subcommittee included, and the House passed, a \$4 million increase for this initiative in the FY20 budget, but it was not included in the final House-Senate agreement.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. We look forward to working with the subcommittee on these most important issues as it goes through the FY22 budget process. If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.