STATEMENT
of the
American Association for Clinical Chemistry
to the
U.S. Senate
Committee on Appropriations Labor, Health & Human Services, Education, and Related Agencies Subcommittee

Re: FY2024 Budget Requests – Centers for Disease Control and Preventions
Presented by Shannon Haymond, PhD, DABCC, FAACC
President, AACC

May 18, 2023

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to provide testimony to the Senate Appropriations Subcommittee on Labor, Health & Human Services, Education, and Related Agencies regarding our nation's fiscal year (FY) 2024 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 Sciences, 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 Sciences, Environmental Health Laboratory, to continue its ongoing efforts to harmonize the reporting of clinical laboratory test results, which is vital to providing better, more consistent, and cost-effective 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, it could result in patient harm. Therefore, it is critical that the range of

values used by practitioners to interpret test results are accurate and reflect normal biological changes.

Whereas the reference intervals for adults are generally reliable, there are considerable inconsistencies 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, many current PRIs are outdated and do not reflect normal biologic changes in children. Most laboratories do not have access to appropriate pediatric samples to create their own PRIs and therefore must rely on those outdated PRIs. This situation was highlighted in a recent study in *JAMA Peds 2021*.[1] In addition, having each laboratory develop their own PRIs will add substantial costs to the healthcare system.

Congress had identified improving PRIs as an issue that needs to be addressed. In the accompanying report language to the *Further Consolidated Appropriations Act of 2020,* the legislature requested that CDC develop and submit a plan for addressing this matter. The agency outlined its plan in the Department of Health and Human Services fiscal year 2021 congressional justification to Congress (p. 501-502). 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 that reflect the diversity in the U.S.; and
- utilize its Environmental Health Laboratory (EHL) to generate reference intervals for children and disseminate the information to clinical laboratories. EHL has previously developed common reference intervals used by laboratories and recommended in clinical practice guidelines.

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 is the harmonization of clinical laboratory test results. Although laboratory tests are accurate, many laboratories use different methods to diagnose a condition, resulting in practitioners receiving different numeric values and reference ranges for diagnosing that same condition. This lack of harmonization makes it difficult to develop widely applicable clinical guidelines or performance measures that can better inform health care decision-making.

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[1] Lyle Alicia N. et al, Current State of Pediatric Reference Intervals and the Importance of Correctly Describing the Biochemistry of Child Development: A Review. *JAMA Pediatrics* 2022; 176(7):699-714

Tests that are harmonized (or standardized) provide the same numeric value for a patient, 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.[2] Thus, 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. CDC is the only laboratory in the U.S. that assists laboratories with achieving accurate and harmonized test results, for several high priority disease biomarkers, such as blood lipids.

With additional funding, CDC will be able to ensure its current harmonization activities and expand its efforts to harmonize new biomarkers used to prevent and treat kidney disease, cancer, diabetes, cardiovascular diseases, and diseases of the endocrine system. This will include new and emerging technologies, such as point of care testing devices, used in patient care and public health. AACC and its partners respectfully request that the subcommittee provide an additional $7.2 million ($9.2 million in total) for CDC to continue and advance its harmonization activities. Congress has provided $2 million annually for this program since FY18. 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 FY24 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.

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