

February 22, 2023

The Honorable Tammy Baldwin  
Chair  
Appropriations Subcommittee on  
Labor, Health and Human Services,  
Education, and Related Agencies  
United States Senate  
Washington, D.C. 20510

The Honorable Shelley Moore Capito  
Ranking Member  
Appropriations Subcommittee on  
Labor, Health and Human Services,  
Education, and Related Agencies  
United States Senate  
Washington, D.C. 20510

The Honorable Robert Aderholt  
Chair  
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 Chairwoman Baldwin, Ranking Member Moore Capito, Chairman Aderholt, and Ranking Member DeLauro,

The undersigned organizations are committed to ensuring that our nation's children receive high-quality, appropriate, and equitable healthcare. A key means of achieving this goal is through laboratory tests that provide objective data to healthcare professionals for evaluating the health status of their young patients.

When making a diagnosis, the healthcare professional considers a laboratory test value within the context of a reference interval – a range of numeric values that would be expected in a healthy individual. If the test result falls outside of the reference interval – either higher or lower – the practitioner may order medical intervention to address the condition. If the diagnosis is incorrect for any reason, including a faulty reference interval, it could result in patient harm. Therefore, it is critical that reference intervals be correct.

Whereas reference intervals for adults are generally reliable, there is considerable inconsistency and large gaps in the ranges provided for children. It is imperative that reference intervals accurately reflect the physical development of patients from birth through adolescence to adulthood, including any variations due to race, ethnicity, or gender. Accurate and actionable reference intervals 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 accurate pediatric reference intervals (PRIs).

In December 2019, the House and Senate passed, and the President signed into law, the *Further Consolidated Appropriations Act of 2020*. In the accompanying report language, the two chambers requested that the Centers for Disease Control and Prevention (CDC) develop and

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submit to Congress 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.

According to the CDC they already have the infrastructure in place to achieve this objective. The agency is proposing to:

- Collect clinical samples through its National Health and Nutrition Examination Survey (NHANES), which has the organization and expertise to collect the 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.

The House of Representatives included language in its accompanying report to its FY22 Departments of Labor, Health and Human Services, Education, & Related Agencies appropriations bill encouraging CDC to begin work on this initiative. The agency projects that it will need an additional \$10 million to initiate and advance this vital work.

The undersigned organizations support CDC's approach and urge Congress to provide the agency with the funding needed to improve pediatric reference intervals and ensure equitable and quality care for our country's children. We appreciate your consideration on this matter.

Academy of Clinical Laboratory Physicians and Scientists  
American Academy of Pediatrics  
American Association for Clinical Chemistry  
American Clinical Laboratory Association  
American Medical Technologists  
American Society for Bone and Mineral Research  
American Society for Clinical Laboratory Science  
American Society for Clinical Pathology  
American Society of Andrology  
American Society of Hematology  
American Society of Pediatric Hematology/Oncology  
American Urological Association  
Association of Pediatric Hematology/Oncology Nurses  
Association of Public Health Laboratories  
ARUP Laboratories  
Avalon Healthcare Solutions  
Children's Healthcare of Atlanta  
Children's Hospital Association  
Children's Hospital of Philadelphia  
Children's National Hospital  
Children's Pathology Chiefs  
COLA, Inc.  
College of American Pathologists  
Endocrine Society

International Society of Andrology  
Laboratory Corporation of America Holdings  
National Association of Pediatric Nurse Practitioners  
Quest Diagnostics  
PCOS Challenge: The National Polycystic Ovary Syndrome Association  
Pediatric Endocrine Society  
Seattle Children's Hospital  
Siemens Healthineers  
Society for Reproductive Investigation