

March 18, 2024

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 Chair Baldwin, Ranking Member Moore Capito, Chair 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 these goals are laboratory tests that provide healthcare professionals with objective data to evaluate the health status of their young patients. Unfortunately, providers often do not have the most accurate information to interpret these data and ensure our children receive the best care possible.

Fortunately, the Centers for Disease Control and Prevention (CDC) can address this vital, but underappreciated issue, if Congress provides them with \$10 million to advance this initiative.

To make a diagnosis, healthcare professionals evaluate test results within the context of a normal range of values or reference intervals for the medical condition. If the value is outside of this range, the care team may order medical treatment to address the situation. Therefore, the normal range used to interpret the value must be precise, otherwise the patient could be misdiagnosed, and unnecessary or harmful interventions ordered. While reference intervals are widely available for adults, pediatric reference intervals (PRIs) are often of poor quality or nonexistent.

Many laboratories do not have the resources to obtain the necessary samples from healthy children to develop appropriate normal ranges. Therefore, they rely upon intervals derived from specimens from sick children, which distort the 'true' normal range. Alternatively, adult reference intervals may be used. However, adult ranges do not reflect the different growth and developmental stages of children and can lead to misdiagnosis and inappropriate care.

A national effort is needed to deal with this children's health issue.

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Congress recognized the importance of this issue when it asked CDC to develop and submit a plan outlining how PRIs can be improved in the fiscal year 2020 budget. In 2021, the agency addressed the issue in the Department of Health and Human Services congressional justification to Congress. CDC stated they 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 reference intervals for children and disseminate the information to clinical laboratories. EHL has developed reference intervals in the past through industry standards.

The House of Representatives included report language in its Fiscal Year 2022 Departments of Labor, Health and Human Services, Education, & Related Agencies appropriations bill encouraging CDC to begin working on this initiative. However, the agency projects that it will need an additional \$10 million to initiate and advance this vital work.

The undersigned organizations support the CDC's approach and urge Congress to provide the funding needed to improve PRIs and ensure quality and equitable care for our country's children. We are asking Congress to appropriate an additional \$10 million to CDC's FY 2025 budget for Environmental Health to fund this important initiative. We appreciate your consideration on this matter.

Academy of Clinical Laboratory Physicians and Scientists
American Academy of Pediatrics
American Association of Nurse Practitioners
American Clinical Laboratory Association
American College of Clinical Pharmacy
American Medical Technologists
American Society of Andrology
American Society for Bone and Mineral Research
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
American Society of Hematology
American Society of Pediatric Hematology/Oncology
American Urological Association
ARUP Laboratories
Association for Diagnostics & Laboratory Medicine
Association of Maternal & Child Health Programs
Association of Pathology Chairs
Association of Pediatric Hematology/Oncology Nurses
Association of Public Health Laboratories
Association of Schools and Programs of Public Health
Avalon Healthcare Solutions
Children's Healthcare of Atlanta

Children's Hospital Association
Children's Hospital Colorado
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
National Hispanic Medical Association
National Rural Health Association
PCOS Challenge: The National Polycystic Ovary Syndrome Association
Pediatric Endocrine Society
Quest Diagnostics
Seattle Children's Hospital
Siemens Healthineers
Society for Reproductive Investigation
Society for Pediatric Pathology
University of Pittsburgh Medical Center (UPMC) Health System