

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